

In the Senate of the United States,

July 7, 2003.

Resolved, That the bill from the House of Representatives (H.R. 1) entitled “An Act to amend title XVIII of the Social Security Act to provide for a voluntary program for prescription drug coverage under the Medicare Program, to modernize the Medicare Program, to amend the Internal Revenue Code of 1986 to allow a deduction to individuals for amounts contributed to health savings security accounts and health savings accounts, to provide for the disposition of unused health benefits in cafeteria plans and flexible spending arrangements, and for other purposes.”, do pass with the following

AMENDMENTS:

Strike out all after the enacting clause and insert:

- 1 ***SECTION 1. SHORT TITLE; AMENDMENTS TO SOCIAL SECU-***
2 ***RITY ACT; REFERENCES TO BIPA AND SEC-***
3 ***RETARY; TABLE OF CONTENTS.***
4 *(a) SHORT TITLE.—This Act may be cited as the “Pre-*
5 *scription Drug and Medicare Improvement Act of 2003”.*

1 (b) *AMENDMENTS TO SOCIAL SECURITY ACT.*—*Except*
 2 *as otherwise specifically provided, whenever in this Act an*
 3 *amendment is expressed in terms of an amendment to or*
 4 *repeal of a section or other provision, the reference shall*
 5 *be considered to be made to that section or other provision*
 6 *of the Social Security Act.*

7 (c) *BIPA; SECRETARY.*—*In this Act:*

8 (1) *BIPA.*—*The term “BIPA” means the Medi-*
 9 *care, Medicaid, and SCHIP Benefits Improvement*
 10 *and Protection Act of 2000, as enacted into law by*
 11 *section 1(a)(6) of Public Law 106–554.*

12 (2) *SECRETARY.*—*The term “Secretary” means*
 13 *the Secretary of Health and Human Services.*

14 (d) *TABLE OF CONTENTS.*—*The table of contents of*
 15 *this Act is as follows:*

Sec. 1. Short title; amendments to Social Security Act; references to BIPA and Secretary; table of contents.

TITLE I—MEDICARE PRESCRIPTION DRUG BENEFIT

Subtitle A—Medicare Voluntary Prescription Drug Delivery Program

Sec. 101. Medicare voluntary prescription drug delivery program.

“PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY PROGRAM

“Sec. 1860D. Definitions; treatment of references to provisions in Medicare Advantage program.

“Subpart 1—Establishment of Voluntary Prescription Drug Delivery Program

“Sec. 1860D–1. Establishment of voluntary prescription drug delivery program.

“Sec. 1860D–2. Enrollment under program.

“Sec. 1860D–3. Election of a Medicare Prescription Drug plan.

“Sec. 1860D–4. Providing information to beneficiaries.

“Sec. 1860D–5. Beneficiary protections.

“Sec. 1860D–6. Prescription drug benefits.

“Sec. 1860D–7. Requirements for entities offering Medicare Prescription Drug plans; establishment of standards.

“Subpart 2—Prescription Drug Delivery System

- “Sec. 1860D–10. Establishment of service areas.*
- “Sec. 1860D–11. Publication of risk adjusters.*
- “Sec. 1860D–12. Submission of bids for proposed Medicare Prescription Drug plans.*
- “Sec. 1860D–13. Approval of proposed Medicare Prescription Drug plans.*
- “Sec. 1860D–14. Computation of monthly standard prescription drug coverage premiums.*
- “Sec. 1860D–15. Computation of monthly national average premium.*
- “Sec. 1860D–16. Payments to eligible entities.*
- “Sec. 1860D–17. Computation of monthly beneficiary obligation.*
- “Sec. 1860D–18. Collection of monthly beneficiary obligation.*
- “Sec. 1860D–19. Premium and cost-sharing subsidies for low-income individuals.*
- “Sec. 1860D–20. Reinsurance payments for expenses incurred in providing prescription drug coverage above the annual out-of-pocket threshold.*
- “Sec. 1860D–21. Direct subsidy for sponsor of a qualified retiree prescription drug plan for plan enrollees eligible for, but not enrolled in, this part.*
- “Sec. 1860D–22. Direct subsidies for qualified State offering a State pharmaceutical assistance program for program enrollees eligible for, but not enrolled in, this part.*

“Subpart 3—Miscellaneous Provisions

- “Sec. 1860D–25. Prescription Drug Account in the Federal Supplementary Medical Insurance Trust Fund.*
- “Sec. 1860D–26. Other related provisions.*

- Sec. 102. Study and report on permitting part B only individuals to enroll in medicare voluntary prescription drug delivery program.*
- Sec. 103. Rules relating to medigap policies that provide prescription drug coverage.*
- Sec. 104. Medicaid and other amendments related to low-income beneficiaries.*
- Sec. 105. Expansion of membership and duties of Medicare Payment Advisory Commission (MedPAC).*
- Sec. 106. Study regarding variations in spending and drug utilization.*
- Sec. 107. Limitation on prescription drug benefits of Members of Congress.*
- Sec. 108. Protecting seniors with cancer.*
- Sec. 109. Protecting seniors with cardiovascular disease, cancer, or Alzheimer’s disease.*
- Sec. 110. Review and report on current standards of practice for pharmacy services provided to patients in nursing facilities.*
- Sec. 110A. Medication therapy management assessment program.*

Subtitle B—Medicare Prescription Drug Discount Card and Transitional Assistance for Low-Income Beneficiaries

- Sec. 111. Medicare prescription drug discount card and transitional assistance for low-income beneficiaries.*

Subtitle C—Standards for Electronic Prescribing

Sec. 121. Standards for electronic prescribing.

Subtitle D—Other Provisions

Sec. 131. Additional requirements for annual financial report and oversight on medicare program.

Sec. 132. Trustees' report on medicare's unfunded obligations.

Sec. 133. Pharmacy benefit managers transparency requirements.

Sec. 134. Office of the Medicare Beneficiary Advocate.

TITLE II—MEDICAREADVANTAGE

Subtitle A—MedicareAdvantage Competition

Sec. 201. Eligibility, election, and enrollment.

Sec. 202. Benefits and beneficiary protections.

Sec. 203. Payments to MedicareAdvantage organizations.

Sec. 204. Submission of bids; premiums.

Sec. 205. Special rules for prescription drug benefits.

Sec. 206. Facilitating employer participation.

Sec. 207. Administration by the Center for Medicare Choices.

Sec. 208. Conforming amendments.

Sec. 209. Effective date.

Sec. 210. Improvements in MedicareAdvantage benchmark determinations.

Subtitle B—Preferred Provider Organizations

Sec. 211. Establishment of MedicareAdvantage preferred provider program option.

Subtitle C—Other Managed Care Reforms

Sec. 221. Extension of reasonable cost contracts.

Sec. 222. Specialized Medicare+Choice plans for special needs beneficiaries.

Sec. 223. Payment by PACE providers for medicare and medicaid services furnished by noncontract providers.

Sec. 224. Institute of Medicine evaluation and report on health care performance measures.

Sec. 225. Expanding the work of medicare quality improvement organizations to include parts C and D.

Sec. 226. Extension of demonstration for ESRD managed care.

SUBTITLE D—EVALUATION OF ALTERNATIVE PAYMENT AND DELIVERY SYSTEMS

Sec. 231. Establishment of alternative payment system for preferred provider organizations in highly competitive regions.

Sec. 232. Fee-for-service modernization projects.

SUBTITLE E—NATIONAL BIPARTISAN COMMISSION ON MEDICARE REFORM

Sec. 241. MedicareAdvantage goal; establishment of Commission.

Sec. 242. National bipartisan commission on medicare reform.

Sec. 243. Congressional consideration of reform proposals.

Sec. 244. Authorization of appropriations.

TITLE III—CENTER FOR MEDICARE CHOICES

Sec. 301. Establishment of the Center for Medicare Choices.

Sec. 302. Miscellaneous administrative provisions.

TITLE IV—MEDICARE FEE-FOR-SERVICE IMPROVEMENTS

Subtitle A—Provisions Relating to Part A

Sec. 401. Equalizing urban and rural standardized payment amounts under the medicare inpatient hospital prospective payment system.

Sec. 402. Adjustment to the medicare inpatient hospital PPS wage index to revise the labor-related share of such index.

Sec. 403. Medicare inpatient hospital payment adjustment for low-volume hospitals.

Sec. 404. Fairness in the medicare disproportionate share hospital (DSH) adjustment for rural hospitals.

Sec. 404A. Medpac study and report regarding medicare Disproportionate Share Hospital (DSH) adjustment payments.

Sec. 405. Critical access hospital (CAH) improvements.

Sec. 406. Authorizing use of arrangements to provide core hospice services in certain circumstances.

Sec. 407. Services provided to hospice patients by nurse practitioners, clinical nurse specialists, and physician assistants.

Sec. 408. Authority to include costs of training of psychologists in payments to hospitals under medicare.

Sec. 409. Revision of Federal rate for hospitals in Puerto Rico.

Sec. 410. Exception to initial residency period for geriatric residency or fellowship programs.

Sec. 411. Clarification of congressional intent regarding the counting of residents in a nonprovider setting and a technical amendment regarding the 3-year rolling average and the IME ratio.

Sec. 412. Limitation on charges for inpatient hospital contract health services provided to Indians by medicare participating hospitals.

Sec. 413. GAO study and report on appropriateness of payments under the prospective payment system for inpatient hospital services.

Sec. 414. Rural community hospital demonstration program.

Sec. 415. Critical access hospital improvement demonstration program.

Sec. 416. Treatment of grandfathered long-term care hospitals.

Sec. 417. Treatment of certain entities for purposes of payments under the medicare program.

Sec. 418. Revision of the indirect medical education (IME) adjustment percentage.

Sec. 419. Calculation of wage indices for hospitals.

Sec. 420. Conforming changes regarding federally qualified health centers.

Sec. 420A. Increase for hospitals with disproportionate indigent care revenues.

Sec. 420B. Treatment of grandfathered long-term care hospitals.

Subtitle B—Provisions Relating to Part B

Sec. 421. Establishment of floor on geographic adjustments of payments for physicians' services.

Sec. 422. Medicare incentive payment program improvements.

Sec. 423. Extension of hold harmless provisions for small rural hospitals and treatment of certain sole community hospitals to limit decline in payment under the OPD PPS.

- Sec. 424. Increase in payments for certain services furnished by small rural and sole community hospitals under medicare prospective payment system for hospital outpatient department services.*
- Sec. 425. Temporary increase for ground ambulance services.*
- Sec. 426. Ensuring appropriate coverage of air ambulance services under ambulance fee schedule.*
- Sec. 427. Treatment of certain clinical diagnostic laboratory tests furnished by a sole community hospital.*
- Sec. 428. Improvement in rural health clinic reimbursement.*
- Sec. 429. Elimination of consolidated billing for certain services under the medicare PPS for skilled nursing facility services.*
- Sec. 430. Freeze in payments for certain items of durable medical equipment and certain orthotics; establishment of quality standards and accreditation requirements for DME providers.*
- Sec. 431. Application of coinsurance and deductible for clinical diagnostic laboratory tests.*
- Sec. 432. Basing medicare payments for covered outpatient drugs on market prices.*
- Sec. 433. Indexing part B deductible to inflation.*
- Sec. 434. Revisions to reassignment provisions.*
- Sec. 435. Extension of treatment of certain physician pathology services under medicare.*
- Sec. 436. Adequate reimbursement for outpatient pharmacy therapy under the hospital outpatient PPS.*
- Sec. 437. Limitation of application of functional equivalence standard.*
- Sec. 438. Medicare coverage of routine costs associated with certain clinical trials.*
- Sec. 439. Waiver of part B late enrollment penalty for certain military retirees; special enrollment period.*
- Sec. 440. Demonstration of coverage of chiropractic services under medicare.*
- Sec. 441. Medicare health care quality demonstration programs.*
- Sec. 442. Medicare complex clinical care management payment demonstration.*
- Sec. 443. Medicare fee-for-service care coordination demonstration program.*
- Sec. 444. GAO study of geographic differences in payments for physicians' services.*
- Sec. 445. Improved payment for certain mammography services.*
- Sec. 446. Improvement of outpatient vision services under Part B.*
- Sec. 447. GAO study and report on the propagation of concierge care.*
- Sec. 448. Coverage of marriage and family therapist services and mental health counselor services under Part B of the medicare program.*
- Sec. 449. Medicare demonstration project for direct access to physical therapy services.*
- Sec. 450. Demonstration project to clarify the definition of homebound.*
- Sec. 450A. Demonstration project for exclusion of brachytherapy devices from prospective payment system for outpatient hospital services.*
- Sec. 450B. Reimbursement for total body orthotic management for certain nursing home patients.*
- Sec. 450C. Authorization of reimbursement for all medicare part B services furnished by certain Indian hospitals and clinics.*
- Sec. 450D. Coverage of cardiovascular screening tests.*
- Sec. 450E. Medicare coverage of self-injected biologicals.*
- Sec. 450F. Extension of medicare secondary payer rules for individuals with end-stage renal disease.*
- Sec. 450G. Requiring the Internal Revenue Service to deposit installment agreement and other fees in the Treasury as miscellaneous receipts.*

- Sec. 450H. Increasing types of originating telehealth sites and facilitating the provision of telehealth services across State lines.*
- Sec. 450I. Demonstration project for coverage of surgical first assisting services of certified registered nurse first assistants.*
- Sec. 450J. Equitable treatment for children's hospitals.*
- Sec. 450K. Treatment of physicians' services furnished in Alaska.*
- Sec. 450L. Demonstration project to examine what weight loss weight management services can cost effectively reach the same result as the NIH Diabetes Primary Prevention Trial study: A 50 percent reduction in the risk for type 2 diabetes for individuals who have impaired glucose tolerance and are obese.*

Subtitle C—Provisions Relating to Parts A and B

- Sec. 451. Increase for home health services furnished in a rural area.*
- Sec. 452. Limitation on reduction in area wage adjustment factors under the prospective payment system for home health services.*
- Sec. 453. Clarifications to certain exceptions to medicare limits on physician referrals.*
- Sec. 454. Demonstration program for substitute adult day services.*
- Sec. 455. MEDPAC study on medicare payments and efficiencies in the health care system.*
- Sec. 456. Medicare coverage of kidney disease education services.*
- Sec. 457. Frontier extended stay clinic demonstration project.*
- Sec. 458. Improvements in national coverage determination process to respond to changes in technology.*
- Sec. 459. Increase in medicare payment for certain home health services.*
- Sec. 460. Frontier extended stay clinic demonstration project.*
- Sec. 461. Medicare secondary payor (MSP) provisions.*
- Sec. 462. Medicare pancreatic islet cell transplant demonstration project.*
- Sec. 463. Increase in medicare payment for certain home health services.*
- Sec. 464. Sense of the Senate concerning medicare payment update for physicians and other health professionals.*

TITLE V—MEDICARE APPEALS, REGULATORY, AND CONTRACTING IMPROVEMENTS

Subtitle A—Regulatory Reform

- Sec. 501. Rules for the publication of a final regulation based on the previous publication of an interim final regulation.*
- Sec. 502. Compliance with changes in regulations and policies.*
- Sec. 503. Report on legal and regulatory inconsistencies.*
- Sec. 504. Streamlining and simplification of medicare regulations.*

Subtitle B—Appeals Process Reform

- Sec. 511. Submission of plan for transfer of responsibility for medicare appeals.*
- Sec. 512. Expedited access to judicial review.*
- Sec. 513. Expedited review of certain provider agreement determinations.*
- Sec. 514. Revisions to medicare appeals process.*
- Sec. 515. Hearing rights related to decisions by the Secretary to deny or not renew a medicare enrollment agreement; consultation before changing provider enrollment forms.*
- Sec. 516. Appeals by providers when there is no other party available.*
- Sec. 517. Provider access to review of local coverage determinations.*
- Sec. 518. Revisions to appeals timeframes.*

Sec. 519. Elimination of requirement to use Social Security Administration Administrative Law Judges.

Sec. 520. Elimination of requirement for de novo review by the departmental appeals board.

Subtitle C—Contracting Reform

Sec. 521. Increased flexibility in medicare administration.

Subtitle D—Education and Outreach Improvements

Sec. 531. Provider education and technical assistance.

Sec. 532. Access to and prompt responses from medicare contractors.

Sec. 533. Reliance on guidance.

Sec. 534. Medicare provider ombudsman.

Sec. 535. Beneficiary outreach demonstration programs.

Subtitle E—Review, Recovery, and Enforcement Reform

Sec. 541. Prepayment review.

Sec. 542. Recovery of overpayments.

Sec. 543. Process for correction of minor errors and omissions on claims without pursuing appeals process.

Sec. 544. Authority to waive a program exclusion.

SUBTITLE F—OTHER IMPROVEMENTS

Sec. 551. Inclusion of additional information in notices to beneficiaries about skilled nursing facility and hospital benefits.

Sec. 552. Information on medicare-certified skilled nursing facilities in hospital discharge plans.

Sec. 553. Evaluation and management documentation guidelines consideration.

Sec. 554. Council for Technology and Innovation.

Sec. 555. Treatment of certain dental claims.

TITLE VI—OTHER PROVISIONS

Sec. 601. Increase in medicaid DSH allotments for fiscal years 2004 and 2005.

Sec. 602. Increase in floor for treatment as an extremely low DSH State under the medicaid program for fiscal years 2004 and 2005.

Sec. 603. Increased reporting requirements to ensure the appropriateness of payment adjustments to disproportionate share hospitals under the medicaid program.

Sec. 604. Clarification of inclusion of inpatient drug prices charged to certain public hospitals in the best price exemptions for the medicaid drug rebate program.

Sec. 605. Assistance with coverage of legal immigrants under the medicaid program and SCHIP.

Sec. 606. Establishment of consumer ombudsman account.

Sec. 607. GAO study regarding impact of assets test for low-income beneficiaries.

Sec. 608. Health care infrastructure improvement.

Sec. 609. Capital infrastructure revolving loan program.

Sec. 610. Federal reimbursement of emergency health services furnished to undocumented aliens.

Sec. 611. Increase in appropriation to the health care fraud and abuse control account.

Sec. 612. Increase in civil penalties under the False Claims Act.

- Sec. 613. Increase in civil monetary penalties under the Social Security Act.*
- Sec. 614. Extension of customs user fees.*
- Sec. 615. Reimbursement for federally qualified health centers participating in medicare managed care.*
- Sec. 616. Provision of information on advance directives.*
- Sec. 617. Sense of the Senate regarding implementation of the Prescription Drug and Medicare Improvement Act of 2003.*
- Sec. 618. Extension of municipal health service demonstration projects.*
- Sec. 619. Study on making prescription pharmaceutical information accessible for blind and visually-impaired individuals.*
- Sec. 620. Health care that works for all americans-citizens health care working group.*
- Sec. 621. GAO study of pharmaceutical price controls and patent protections in the G-7 countries.*
- Sec. 622. Sense of the Senate concerning medicare payment update for physicians and other health professionals.*
- Sec. 623. Restoration of Federal Hospital Insurance Trust Fund.*
- Sec. 624. Safety net organizations and Patient Advisory Commission.*
- Sec. 625. Urban health provider adjustment.*
- Sec. 626. Committee on drug compounding.*
- Sec. 627. Sense of the Senate concerning the structure of medicare reform and the prescription drug benefit.*
- Sec. 628. Sense of the Senate regarding the establishment of a nationwide permanent lifestyle modification program for medicare beneficiaries.*
- Sec. 629. Sense of the Senate on payment reductions under medicare physician fee schedule.*
- Sec. 630. Temporary suspension of oasis requirement for collection of data on non-medicare and non-medicaid patients.*
- Sec. 631. Employer flexibility.*
- Sec. 632. One Hundred percent FMAP for medical assistance provided to a Native Hawaiian through a federally-qualified health center or a Native Hawaiian health care system under the medicaid program.*
- Sec. 633. Extension of moratorium.*
- Sec. 634. GAO study of pharmaceutical price controls and patent protections in the G-7 countries.*
- Sec. 635. Safety Net Organizations and Patient Advisory Commission.*
- Sec. 636. Establishment of program to prevent abuse of nursing facility residents.*
- Sec. 637. Office of Rural Health Policy Improvements.*

TITLE VII—ACCESS TO AFFORDABLE PHARMACEUTICALS

- Sec. 701. Short title.*
- Sec. 702. 30-month stay-of-effectiveness period.*
- Sec. 703. Forfeiture of 180-day exclusivity period.*
- Sec. 704. Bioavailability and bioequivalence.*
- Sec. 705. Remedies for infringement.*
- Sec. 706. Conforming amendments.*

TITLE VIII—IMPORTATION OF PRESCRIPTION DRUGS

- Sec. 801. Importation of prescription drugs.*

TITLE IX—DRUG COMPETITION ACT OF 2003

- Sec. 901. Short title.*

Sec. 902. Findings.
Sec. 903. Purposes.
Sec. 904. Definitions.
Sec. 905. Notification of agreements.
Sec. 906. Filing deadlines.
Sec. 907. Disclosure exemption.
Sec. 908. Enforcement.
Sec. 909. Rulemaking.
Sec. 910. Savings clause.
Sec. 911. Effective date.

1 ***TITLE I—MEDICARE***
 2 ***PRESCRIPTION DRUG BENEFIT***
 3 ***Subtitle A—Medicare Voluntary***
 4 ***Prescription Drug Delivery Pro-***
 5 ***gram***

6 ***SEC. 101. MEDICARE VOLUNTARY PRESCRIPTION DRUG DE-***
 7 ***LIVERY PROGRAM.***

8 (a) *ESTABLISHMENT.*—*Title XVIII (42 U.S.C. 1395 et*
 9 *seq.) is amended by redesignating part D as part E and*
 10 *by inserting after part C the following new part:*

11 “*PART D—VOLUNTARY PRESCRIPTION DRUG DELIVERY*
 12 *PROGRAM*

13 “*DEFINITIONS; TREATMENT OF REFERENCES TO*
 14 *PROVISIONS IN MEDICAREADVANTAGE PROGRAM*

15 “*SEC. 1860D. (a) DEFINITIONS.*—*In this part:*

16 “(1) *ADMINISTRATOR.*—*The term ‘Adminis-*
 17 *trator’ means the Administrator of the Center for*
 18 *Medicare Choices as established under section 1808.*

19 “(2) *COVERED DRUG.*—

1 “(A) *IN GENERAL.*—*Except as provided in*
 2 *subparagraphs (B), (C), and (D), the term ‘cov-*
 3 *ered drug’ means—*

4 “(i) *a drug that may be dispensed only*
 5 *upon a prescription and that is described in*
 6 *clause (i) or (ii) of subparagraph (A) of sec-*
 7 *tion 1927(k)(2); or*

8 “(ii) *a biological product described in*
 9 *clauses (i) through (iii) of subparagraph*
 10 *(B) of such section; or*

11 “(iii) *insulin described in subpara-*
 12 *graph (C) of such section (including sy-*
 13 *ringes, and necessary medical supplies asso-*
 14 *ciated with the administration of insulin,*
 15 *as defined by the Administrator);*

16 *and such term includes a vaccine licensed under*
 17 *section 351 of the Public Health Service Act and*
 18 *any use of a covered drug for a medically accept-*
 19 *ed indication (as defined in section 1927(k)(6)).*

20 “(B) *EXCLUSIONS.*—

21 “(i) *IN GENERAL.*—*The term ‘covered*
 22 *drug’ does not include drugs or classes of*
 23 *drugs, or their medical uses, which may be*
 24 *excluded from coverage or otherwise re-*
 25 *stricted under section 1927(d)(2), other than*

1 *subparagraph (E) thereof (relating to smok-*
 2 *ing cessation agents), or under section*
 3 *1927(d)(3).*

4 “(ii) *AVOIDANCE OF DUPLICATE COV-*
 5 *ERAGE.—A drug prescribed for an indi-*
 6 *vidual that would otherwise be a covered*
 7 *drug under this part shall not be so consid-*
 8 *ered if payment for such drug is available*
 9 *under part A or B, but shall be so consid-*
 10 *ered if such payment is not available under*
 11 *part A or B or because benefits under such*
 12 *parts have been exhausted.*

13 “(C) *APPLICATION OF FORMULARY RESTRIC-*
 14 *TIONS.—A drug prescribed for an individual*
 15 *that would otherwise be a covered drug under*
 16 *this part shall not be so considered under a plan*
 17 *if the plan excludes the drug under a formulary*
 18 *and such exclusion is not successfully resolved*
 19 *under subsection (d) or (e)(2) of section 1860D–*
 20 *5.*

21 “(D) *APPLICATION OF GENERAL EXCLUSION*
 22 *PROVISIONS.—A Medicare Prescription Drug*
 23 *plan or a MedicareAdvantage plan may exclude*
 24 *from qualified prescription drug coverage any*
 25 *covered drug—*

1 “(i) for which payment would not be
2 made if section 1862(a) applied to part D;
3 or

4 “(ii) which are not prescribed in ac-
5 cordance with the plan or this part.

6 Such exclusions are determinations subject to re-
7 consideration and appeal pursuant to section
8 1860D–5(e).

9 “(3) *ELIGIBLE BENEFICIARY.*—The term ‘eligible
10 beneficiary’ means an individual who is entitled to,
11 or enrolled for, benefits under part A and enrolled
12 under part B (other than a dual eligible individual,
13 as defined in section 1860D–19(a)(4)(E)).

14 “(4) *ELIGIBLE ENTITY.*—The term ‘eligible enti-
15 ty’ means any risk-bearing entity that the Adminis-
16 trator determines to be appropriate to provide eligible
17 beneficiaries with the benefits under a Medicare Pre-
18 scription Drug plan, including—

19 “(A) a pharmaceutical benefit management
20 company;

21 “(B) a wholesale or retail pharmacist deliv-
22 ery system;

23 “(C) an insurer (including an insurer that
24 offers medicare supplemental policies under sec-
25 tion 1882);

1 “(D) any other risk-bearing entity; or

2 “(E) any combination of the entities de-
3 scribed in subparagraphs (A) through (D).

4 “(5) *INITIAL COVERAGE LIMIT*.—The term ‘ini-
5 tial coverage limit’ means the limit as established
6 under section 1860D–6(c)(3), or, in the case of cov-
7 erage that is not standard prescription drug coverage,
8 the comparable limit (if any) established under the
9 coverage.

10 “(6) *MEDICAREADVANTAGE ORGANIZATION*;
11 *MEDICAREADVANTAGE PLAN*.—The terms
12 ‘MedicareAdvantage organization’ and
13 ‘MedicareAdvantage plan’ have the meanings given
14 such terms in subsections (a)(1) and (b)(1), respec-
15 tively, of section 1859 (relating to definitions relating
16 to MedicareAdvantage organizations).

17 “(7) *MEDICARE PRESCRIPTION DRUG PLAN*.—
18 The term ‘Medicare Prescription Drug plan’ means
19 prescription drug coverage that is offered under a pol-
20 icy, contract, or plan—

21 “(A) that has been approved under section
22 1860D–13; and

23 “(B) by an eligible entity pursuant to, and
24 in accordance with, a contract between the Ad-

1 *ministrator and the entity under section 1860D–*
 2 *7(b).*

3 “(8) *PRESCRIPTION DRUG ACCOUNT.*—*The term*
 4 *‘Prescription Drug Account’ means the Prescription*
 5 *Drug Account (as established under section 1860D–*
 6 *25) in the Federal Supplementary Medical Insurance*
 7 *Trust Fund under section 1841.*

8 “(9) *QUALIFIED PRESCRIPTION DRUG COV-*
 9 *ERAGE.*—*The term ‘qualified prescription drug cov-*
 10 *erage’ means the coverage described in section 1860D–*
 11 *6(a)(1).*

12 “(10) *STANDARD PRESCRIPTION DRUG COV-*
 13 *ERAGE.*—*The term ‘standard prescription drug cov-*
 14 *erage’ means the coverage described in section 1860D–*
 15 *6(c).*

16 “(b) *APPLICATION OF MEDICAREADVANTAGE PROVI-*
 17 *SIONS UNDER THIS PART.*—*For purposes of applying pro-*
 18 *visions of part C under this part with respect to a Medicare*
 19 *Prescription Drug plan and an eligible entity, unless other-*
 20 *wise provided in this part such provisions shall be applied*
 21 *as if—*

22 “(1) *any reference to a MedicareAdvantage plan*
 23 *included a reference to a Medicare Prescription Drug*
 24 *plan;*

1 “(2) any reference to a provider-sponsored orga-
 2 nization included a reference to an eligible entity;

3 “(3) any reference to a contract under section
 4 1857 included a reference to a contract under section
 5 1860D–7(b); and

6 “(4) any reference to part C included a reference
 7 to this part.

8 “Subpart 1—Establishment of Voluntary Prescription
 9 Drug Delivery Program

10 “ESTABLISHMENT OF VOLUNTARY PRESCRIPTION DRUG
 11 DELIVERY PROGRAM

12 “SEC. 1860D–1. (a) PROVISION OF BENEFIT.—

13 “(1) IN GENERAL.—The Administrator shall pro-
 14 vide for and administer a voluntary prescription
 15 drug delivery program under which each eligible bene-
 16 ficiary enrolled under this part shall be provided with
 17 access to qualified prescription drug coverage as fol-
 18 lows:

19 “(A) MEDICAREADVANTAGE ENROLLEES RE-
 20 CEIVE COVERAGE THROUGH
 21 MEDICAREADVANTAGE PLAN.—

22 “(i) IN GENERAL.—Except as provided
 23 in clause (ii), an eligible beneficiary who is
 24 enrolled under this part and enrolled in a
 25 MedicareAdvantage plan offered by a

1 *MedicareAdvantage organization shall re-*
 2 *ceive coverage of benefits under this part*
 3 *through such plan.*

4 “(ii) *EXCEPTION FOR ENROLLEES IN*
 5 *MEDICAREADVANTAGE MSA PLANS.—An eli-*
 6 *gible beneficiary who is enrolled under this*
 7 *part and enrolled in an MSA plan under*
 8 *part C shall receive coverage of benefits*
 9 *under this part through enrollment in a*
 10 *Medicare Prescription Drug plan that is of-*
 11 *fered in the geographic area in which the*
 12 *beneficiary resides. For purposes of this*
 13 *part, the term ‘MSA plan’ has the meaning*
 14 *given such term in section 1859(b)(3).*

15 “(iii) *EXCEPTION FOR ENROLLEES IN*
 16 *MEDICAREADVANTAGE PRIVATE FEE-FOR-*
 17 *SERVICE PLANS.—An eligible beneficiary*
 18 *who is enrolled under this part and enrolled*
 19 *in a private fee-for-service plan under part*
 20 *C shall—*

21 “(i) *receive benefits under this*
 22 *part through such plan if the plan pro-*
 23 *vides qualified prescription drug cov-*
 24 *erage; and*

1 “(ii) if the plan does not provide
 2 qualified prescription drug coverage,
 3 receive coverage of benefits under this
 4 part through enrollment in a Medicare
 5 Prescription Drug plan that is offered
 6 in the geographic area in which the
 7 beneficiary resides. For purposes of
 8 this part, the term ‘private fee-for-serv-
 9 ice plan’ has the meaning given such
 10 term in section 1859(b)(2).

11 “(B) FEE-FOR-SERVICE ENROLLEES RE-
 12 CEIVE COVERAGE THROUGH A MEDICARE PRE-
 13 SCRIPTION DRUG PLAN.—An eligible beneficiary
 14 who is enrolled under this part but is not en-
 15 rolled in a Medicare Advantage plan (except for
 16 an MSA plan or a private fee-for-service plan
 17 that does not provide qualified prescription drug
 18 coverage) shall receive coverage of benefits under
 19 this part through enrollment in a Medicare Pre-
 20 scription Drug plan that is offered in the geo-
 21 graphic area in which the beneficiary resides.

22 “(2) VOLUNTARY NATURE OF PROGRAM.—Noth-
 23 ing in this part shall be construed as requiring an el-
 24 igible beneficiary to enroll in the program under this
 25 part.

1 “(3) *SCOPE OF BENEFITS.*—Pursuant to section
 2 1860D–6(b)(3)(C), the program established under this
 3 part shall provide for coverage of all therapeutic cat-
 4 egories and classes of covered drugs (although not nec-
 5 essarily for all drugs within such categories and class-
 6 es).

7 “(4) *PROGRAM TO BEGIN IN 2006.*—The Adminis-
 8 trator shall establish the program under this part in
 9 a manner so that benefits are first provided beginning
 10 on January 1, 2006.

11 “(b) *ACCESS TO ALTERNATIVE PRESCRIPTION DRUG*
 12 *COVERAGE.*—In the case of an eligible beneficiary who has
 13 creditable prescription drug coverage (as defined in section
 14 1860D–2(b)(1)(F)), such beneficiary—

15 “(1) may continue to receive such coverage and
 16 not enroll under this part; and

17 “(2) pursuant to section 1860D–2(b)(1)(C), is
 18 permitted to subsequently enroll under this part with-
 19 out any penalty and obtain access to qualified pre-
 20 scription drug coverage in the manner described in
 21 subsection (a) if the beneficiary involuntarily loses
 22 such coverage.

23 “(c) *FINANCING.*—The costs of providing benefits
 24 under this part shall be payable from the Prescription Drug
 25 Account.

1 “ENROLLMENT UNDER PROGRAM

2 “SEC. 1860D–2. (a) *ESTABLISHMENT OF ENROLL-*
3 *MENT PROCESS.*—

4 “(1) *PROCESS SIMILAR TO PART B ENROLL-*
5 *MENT.*—*The Administrator shall establish a process*
6 *through which an eligible beneficiary (including an*
7 *eligible beneficiary enrolled in a MedicareAdvantage*
8 *plan offered by a MedicareAdvantage organization)*
9 *may make an election to enroll under this part. Such*
10 *process shall be similar to the process for enrollment*
11 *in part B under section 1837, including the deeming*
12 *provisions of such section.*

13 “(2) *CONDITION OF ENROLLMENT.*—*An eligible*
14 *beneficiary must be enrolled under this part in order*
15 *to be eligible to receive access to qualified prescription*
16 *drug coverage.*

17 “(b) *SPECIAL ENROLLMENT PROCEDURES.*—

18 “(1) *LATE ENROLLMENT PENALTY.*—

19 “(A) *INCREASE IN MONTHLY BENEFICIARY*
20 *OBLIGATION.*—*Subject to the succeeding provi-*
21 *sions of this paragraph, in the case of an eligible*
22 *beneficiary whose coverage period under this*
23 *part began pursuant to an enrollment after the*
24 *beneficiary’s initial enrollment period under*
25 *part B (determined pursuant to section 1837(d))*

1 *and not pursuant to the open enrollment period*
2 *described in paragraph (2), the Administrator*
3 *shall establish procedures for increasing the*
4 *amount of the monthly beneficiary obligation*
5 *under section 1860D–17 applicable to such bene-*
6 *ficiary by an amount that the Administrator de-*
7 *termines is actuarially sound for each full 12-*
8 *month period (in the same continuous period of*
9 *eligibility) in which the eligible beneficiary could*
10 *have been enrolled under this part but was not*
11 *so enrolled.*

12 “(B) *PERIODS TAKEN INTO ACCOUNT.—For*
13 *purposes of calculating any 12-month period*
14 *under subparagraph (A), there shall be taken*
15 *into account—*

16 “(i) *the months which elapsed between*
17 *the close of the eligible beneficiary’s initial*
18 *enrollment period and the close of the en-*
19 *rollment period in which the beneficiary en-*
20 *rolled; and*

21 “(ii) *in the case of an eligible bene-*
22 *ficiary who reenrolls under this part, the*
23 *months which elapsed between the date of*
24 *termination of a previous coverage period*

1 *and the close of the enrollment period in*
 2 *which the beneficiary reenrolled.*

3 “(C) *PERIODS NOT TAKEN INTO ACCOUNT.*—

4 “(i) *IN GENERAL.*—For purposes of
 5 *calculating any 12-month period under sub-*
 6 *paragraph (A), subject to clause (ii), there*
 7 *shall not be taken into account months for*
 8 *which the eligible beneficiary can dem-*
 9 *onstrate that the beneficiary had creditable*
 10 *prescription drug coverage (as defined in*
 11 *subparagraph (F)).*

12 “(ii) *BENEFICIARY MUST INVOLUN-*
 13 *TARILY LOSE COVERAGE.*—Clause (i) shall
 14 *only apply with respect to coverage—*

15 “(I) *in the case of coverage de-*
 16 *scribed in clause (ii) of subparagraph*
 17 *(F), if the plan terminates, ceases to*
 18 *provide, or reduces the value of the pre-*
 19 *scription drug coverage under such*
 20 *plan to below the actuarial value of*
 21 *standard prescription drug coverage*
 22 *(as determined under section 1860D–*
 23 *6(f));*

24 “(II) *in the case of coverage de-*
 25 *scribed in clause (i), (iii), or (iv) of*

1 subparagraph (F), if the beneficiary is
 2 involuntarily disenrolled or becomes
 3 ineligible for such coverage; or

4 “(III) in the case of a beneficiary
 5 with coverage described in clause (v) of
 6 subparagraph (F), if the issuer of the
 7 policy terminates coverage under the
 8 policy.

9 “(D) PERIODS TREATED SEPARATELY.—
 10 Any increase in an eligible beneficiary’s monthly
 11 beneficiary obligation under subparagraph (A)
 12 with respect to a particular continuous period of
 13 eligibility shall not be applicable with respect to
 14 any other continuous period of eligibility which
 15 the beneficiary may have.

16 “(E) CONTINUOUS PERIOD OF ELIGI-
 17 BILITY.—

18 “(i) IN GENERAL.—Subject to clause
 19 (ii), for purposes of this paragraph, an eli-
 20 gible beneficiary’s ‘continuous period of eli-
 21 gibility’ is the period that begins with the
 22 first day on which the beneficiary is eligible
 23 to enroll under section 1836 and ends with
 24 the beneficiary’s death.

1 “(ii) *SEPARATE PERIOD.*—Any period
 2 *during all of which an eligible beneficiary*
 3 *satisfied paragraph (1) of section 1836 and*
 4 *which terminated in or before the month*
 5 *preceding the month in which the bene-*
 6 *ficiary attained age 65 shall be a separate*
 7 *‘continuous period of eligibility’ with re-*
 8 *spect to the beneficiary (and each such pe-*
 9 *riod which terminates shall be deemed not*
 10 *to have existed for purposes of subsequently*
 11 *applying this paragraph).*

12 “(F) *CREDITABLE PRESCRIPTION DRUG*
 13 *COVERAGE DEFINED.*—Subject to subparagraph
 14 (G), for purposes of this part, the term ‘cred-
 15 itable prescription drug coverage’ means any of
 16 the following:

17 “(i) *DRUG-ONLY COVERAGE UNDER*
 18 *MEDICAID.*—Coverage of covered outpatient
 19 drugs (as defined in section 1927) under
 20 title XIX or a waiver under 1115 that is
 21 provided to an individual who is not a dual
 22 eligible individual (as defined in section
 23 1860D–19(a)(4)(E)).

24 “(ii) *PRESCRIPTION DRUG COVERAGE*
 25 *UNDER A GROUP HEALTH PLAN.*—Any out-

1 *patient prescription drug coverage under a*
 2 *group health plan, including a health bene-*
 3 *fits plan under chapter 89 of title 5, United*
 4 *States Code (commonly known as the Fed-*
 5 *eral employees health benefits program),*
 6 *and a qualified retiree prescription drug*
 7 *plan (as defined in section 1860D-*
 8 *20(e)(4)).*

9 “(iii) *STATE PHARMACEUTICAL AS-*
 10 *SISTANCE PROGRAM.—Coverage of prescrip-*
 11 *tion drugs under a State pharmaceutical*
 12 *assistance program.*

13 “(iv) *VETERANS’ COVERAGE OF PRE-*
 14 *SCRIPTION DRUGS.—Coverage of prescrip-*
 15 *tion drugs for veterans, and survivors and*
 16 *dependents of veterans, under chapter 17 of*
 17 *title 38, United States Code.*

18 “(v) *PRESCRIPTION DRUG COVERAGE*
 19 *UNDER MEDIGAP POLICIES.—Coverage*
 20 *under a medicare supplemental policy*
 21 *under section 1882 that provides benefits for*
 22 *prescription drugs (whether or not such cov-*
 23 *erage conforms to the standards for pack-*
 24 *ages of benefits under section 1882(p)(1)).*

1 “(G) *REQUIREMENT FOR CREDITABLE COV-*
 2 *ERAGE.*—Coverage described in clauses (i)
 3 *through (v) of subparagraph (F) shall not be*
 4 *considered to be creditable coverage under this*
 5 *part unless the coverage provides coverage of the*
 6 *cost of prescription drugs the actuarial value of*
 7 *which (as defined by the Administrator) to the*
 8 *beneficiary equals or exceeds the actuarial value*
 9 *of standard prescription drug coverage (as deter-*
 10 *mined under section 1860D–6(f)).*

11 “(H) *DISCLOSURE.*—

12 “(i) *IN GENERAL.*—Each entity that
 13 *offers coverage of the type described in*
 14 *clause (ii) (iii), (iv), or (v) of subparagraph*
 15 *(F) shall provide for disclosure, consistent*
 16 *with standards established by the Adminis-*
 17 *trator, of whether the coverage provides cov-*
 18 *erage of the cost of prescription drugs the*
 19 *actuarial value of which (as defined by the*
 20 *Administrator) to the beneficiary equals or*
 21 *exceeds the actuarial value of standard pre-*
 22 *scription drug coverage (as determined*
 23 *under section 1860D–6(f)).*

24 “(ii) *WAIVER OF LIMITATIONS.*—An
 25 *individual may apply to the Administrator*

1 to waive the application of subparagraph
 2 (G) if the individual establishes that the in-
 3 dividual was not adequately informed that
 4 the coverage the beneficiary was enrolled in
 5 did not provide the level of benefits required
 6 in order for the coverage to be considered
 7 creditable coverage under subparagraph (F).

8 “(2) INITIAL ELECTION PERIODS.—

9 “(A) OPEN ENROLLMENT PERIOD FOR CUR-
 10 RENT BENEFICIARIES IN WHICH LATE ENROLL-
 11 MENT PROCEDURES DO NOT APPLY.—In the case
 12 of an individual who is an eligible beneficiary as
 13 of November 1, 2005, there shall be an open en-
 14 rollment period of 6 months beginning on that
 15 date under which such beneficiary may enroll
 16 under this part without the application of the
 17 late enrollment procedures established under
 18 paragraph (1)(A).

19 “(B) INDIVIDUAL COVERED IN FUTURE.—In
 20 the case of an individual who becomes an eligible
 21 beneficiary after such date, there shall be an ini-
 22 tial election period which is the same as the ini-
 23 tial enrollment period under section 1837(d).

1 “(3) *SPECIAL ENROLLMENT PERIOD FOR BENE-*
 2 *FICIARIES WHO INVOLUNTARILY LOSE CREDITABLE*
 3 *PRESCRIPTION DRUG COVERAGE.—*

4 “(A) *ESTABLISHMENT.—The Administrator*
 5 *shall establish a special open enrollment period*
 6 *(as described in subparagraph (B)) for an eligi-*
 7 *ble beneficiary that loses creditable prescription*
 8 *drug coverage.*

9 “(B) *SPECIAL OPEN ENROLLMENT PE-*
 10 *RIOD.—The special open enrollment period de-*
 11 *scribed in this subparagraph is the 63-day pe-*
 12 *riod that begins on—*

13 “(i) *in the case of a beneficiary with*
 14 *coverage described in clause (ii) of para-*
 15 *graph (1)(F), the later of the date on which*
 16 *the plan terminates, ceases to provide, or*
 17 *substantially reduces (as defined by the Ad-*
 18 *ministrator) the value of the prescription*
 19 *drug coverage under such plan or the date*
 20 *the beneficiary is provided with notice of*
 21 *such termination or reduction;*

22 “(ii) *in the case of a beneficiary with*
 23 *coverage described in clause (i), (iii), or (iv)*
 24 *of paragraph (1)(F), the later of the date on*
 25 *which the beneficiary is involuntarily*

1 *disenrolled or becomes ineligible for such*
 2 *coverage or the date the beneficiary is pro-*
 3 *vided with notice of such loss of eligibility;*
 4 *or*

5 *“(iii) in the case of a beneficiary with*
 6 *coverage described in clause (v) of para-*
 7 *graph (1)(F), the latter of the date on which*
 8 *the issuer of the policy terminates coverage*
 9 *under the policy or the date the beneficiary*
 10 *is provided with notice of such termination.*

11 *“(c) PERIOD OF COVERAGE.—*

12 *“(1) IN GENERAL.—Except as provided in para-*
 13 *graph (2) and subject to paragraph (3), an eligible*
 14 *beneficiary’s coverage under the program under this*
 15 *part shall be effective for the period provided in sec-*
 16 *tion 1838, as if that section applied to the program*
 17 *under this part.*

18 *“(2) OPEN AND SPECIAL ENROLLMENT.—*

19 *“(A) OPEN ENROLLMENT.—An eligible bene-*
 20 *ficiary who enrolls under the program under this*
 21 *part pursuant to subsection (b)(2) shall be enti-*
 22 *tled to the benefits under this part beginning on*
 23 *January 1, 2006.*

24 *“(B) SPECIAL ENROLLMENT.—Subject to*
 25 *paragraph (3), an eligible beneficiary who en-*

1 *rolls under the program under this part pursu-*
 2 *ant to subsection (b)(3) shall be entitled to the*
 3 *benefits under this part beginning on the first*
 4 *day of the month following the month in which*
 5 *such enrollment occurs.*

6 “(3) *LIMITATION.*—*Coverage under this part*
 7 *shall not begin prior to January 1, 2006.*

8 “(d) *TERMINATION.*—

9 “(1) *IN GENERAL.*—*The causes of termination*
 10 *specified in section 1838 shall apply to this part in*
 11 *the same manner as such causes apply to part B.*

12 “(2) *COVERAGE TERMINATED BY TERMINATION*
 13 *OF COVERAGE UNDER PART A OR B.*—

14 “(A) *IN GENERAL.*—*In addition to the*
 15 *causes of termination specified in paragraph (1),*
 16 *the Administrator shall terminate an individ-*
 17 *ual’s coverage under this part if the individual*
 18 *is no longer enrolled in both parts A and B.*

19 “(B) *EFFECTIVE DATE.*—*The termination*
 20 *described in subparagraph (A) shall be effective*
 21 *on the effective date of termination of coverage*
 22 *under part A or (if earlier) under part B.*

23 “(3) *PROCEDURES REGARDING TERMINATION OF*
 24 *A BENEFICIARY UNDER A PLAN.*—*The Administrator*
 25 *shall establish procedures for determining the status of*

1 *an eligible beneficiary’s enrollment under this part if*
 2 *the beneficiary’s enrollment in a Medicare Prescrip-*
 3 *tion Drug plan offered by an eligible entity under*
 4 *this part is terminated by the entity for cause (pursu-*
 5 *ant to procedures established by the Administrator*
 6 *under section 1860D–3(a)(1)).*

7 “*ELECTION OF A MEDICARE PRESCRIPTION DRUG PLAN*

8 “*SEC. 1860D–3. (a) IN GENERAL.—*

9 “*(1) PROCESS.—*

10 “*(A) ELECTION.—*

11 “*(i) IN GENERAL.—The Administrator*
 12 *shall establish a process through which an*
 13 *eligible beneficiary who is enrolled under*
 14 *this part but not enrolled in a*
 15 *MedicareAdvantage plan (except for an*
 16 *MSA plan or a private fee-for-service plan*
 17 *that does not provide qualified prescription*
 18 *drug coverage) offered by a*
 19 *MedicareAdvantage organization—*

20 “*(I) shall make an election to en-*
 21 *roll in any Medicare Prescription*
 22 *Drug plan that is offered by an eligible*
 23 *entity and that serves the geographic*
 24 *area in which the beneficiary resides;*
 25 *and*

1 “(II) may make an annual elec-
 2 tion to change the election under this
 3 clause.

4 “(ii) CLARIFICATION REGARDING EN-
 5 ROLLMENT.—The process established under
 6 clause (i) shall include, in the case of an el-
 7 igible beneficiary who is enrolled under this
 8 part but who has failed to make an election
 9 of a Medicare Prescription Drug plan in an
 10 area, for the enrollment in any Medicare
 11 Prescription Drug plan that has been des-
 12 ignated by the Administrator in the area.
 13 The Administrator shall establish a process
 14 for designating a plan or plans in order to
 15 carry out the preceding sentence.

16 “(B) REQUIREMENTS FOR PROCESS.—In es-
 17 tablishing the process under subparagraph (A),
 18 the Administrator shall—

19 “(i) use rules similar to the rules for
 20 enrollment, disenrollment, and termination
 21 of enrollment with a Medicare Advantage
 22 plan under section 1851, including—

23 “(I) the establishment of special
 24 election periods under subsection (e)(4)
 25 of such section; and

1 “(II) the application of the guar-
 2 anteed issue and renewal provisions of
 3 section 1851(g) (other than clause (i)
 4 and the second sentence of clause (ii) of
 5 paragraph (3)(C), relating to default
 6 enrollment); and

7 “(ii) coordinate enrollments,
 8 disenrollments, and terminations of enroll-
 9 ment under part C with enrollments,
 10 disenrollments, and terminations of enroll-
 11 ment under this part.

12 “(2) *FIRST ENROLLMENT PERIOD FOR PLAN EN-*
 13 *ROLLMENT.*—The process developed under paragraph
 14 (1) shall ensure that eligible beneficiaries who enroll
 15 under this part during the open enrollment period
 16 under section 1860D–2(b)(2) are permitted to elect an
 17 eligible entity prior to January 1, 2006, in order to
 18 ensure that coverage under this part is effective as of
 19 such date.

20 “(b) *ENROLLMENT IN A MEDICAREADVANTAGE*
 21 *PLAN.*—

22 “(1) *IN GENERAL.*—An eligible beneficiary who
 23 is enrolled under this part and enrolled in a
 24 MedicareAdvantage plan (except for an MSA plan or
 25 a private fee-for-service plan that does not provide

1 *qualified prescription drug coverage) offered by a*
 2 *MedicareAdvantage organization shall receive access*
 3 *to such coverage under this part through such plan.*

4 “(2) *RULES.—Enrollment in a*
 5 *MedicareAdvantage plan is subject to the rules for en-*
 6 *rollment in such plan under section 1851.*

7 “(c) *INFORMATION TO ENTITIES TO FACILITATE EN-*
 8 *ROLLMENT.—Notwithstanding any other provision of law,*
 9 *the Administrator may provide to each eligible entity with*
 10 *a contract under this part such information about eligible*
 11 *beneficiaries as the Administrator determines to be nec-*
 12 *essary to facilitate efficient enrollment by such beneficiaries*
 13 *with such entities. The Administrator may provide such in-*
 14 *formation only so long as and to the extent necessary to*
 15 *carry out such objective.*

16 “*PROVIDING INFORMATION TO BENEFICIARIES*

17 “*SEC. 1860D–4. (a) ACTIVITIES.—*

18 “(1) *IN GENERAL.—The Administrator shall con-*
 19 *duct activities that are designed to broadly dissemi-*
 20 *nate information to eligible beneficiaries (and pro-*
 21 *spective eligible beneficiaries) regarding the coverage*
 22 *provided under this part.*

23 “(2) *SPECIAL RULE FOR FIRST ENROLLMENT*
 24 *UNDER THE PROGRAM.—The activities described in*
 25 *paragraph (1) shall ensure that eligible beneficiaries*
 26 *are provided with such information at least 30 days*

1 *prior to the first enrollment period described in sec-*
 2 *tion 1860D–3(a)(2).*

3 “(b) *REQUIREMENTS.*—

4 “(1) *IN GENERAL.*—*The activities described in*
 5 *subsection (a) shall—*

6 “(A) *be similar to the activities performed*
 7 *by the Administrator under section 1851(d);*

8 “(B) *be coordinated with the activities per-*
 9 *formed by—*

10 “(i) *the Administrator under such sec-*
 11 *tion; and*

12 “(ii) *the Secretary under section 1804;*
 13 *and*

14 “(C) *provide for the dissemination of infor-*
 15 *mation comparing the plans offered by eligible*
 16 *entities under this part that are available to eli-*
 17 *gible beneficiaries residing in an area.*

18 “(2) *COMPARATIVE INFORMATION.*—*The com-*
 19 *parative information described in paragraph (1)(C)*
 20 *shall include a comparison of the following:*

21 “(A) *BENEFITS.*—*The benefits provided*
 22 *under the plan and the formularies and griev-*
 23 *ance and appeals processes under the plan.*

1 “(B) *MONTHLY BENEFICIARY OBLIGA-*
 2 *TION.—The monthly beneficiary obligation under*
 3 *the plan.*

4 “(C) *QUALITY AND PERFORMANCE.—The*
 5 *quality and performance of the eligible entity of-*
 6 *fering the plan.*

7 “(D) *BENEFICIARY COST-SHARING.—The*
 8 *cost-sharing required of eligible beneficiaries*
 9 *under the plan.*

10 “(E) *CONSUMER SATISFACTION SURVEYS.—*
 11 *The results of consumer satisfaction surveys re-*
 12 *garding the plan and the eligible entity offering*
 13 *such plan (conducted pursuant to section*
 14 *1860D–5(h).*

15 “(F) *ADDITIONAL INFORMATION.—Such ad-*
 16 *ditional information as the Administrator may*
 17 *prescribe.*

18 “*BENEFICIARY PROTECTIONS*

19 “*SEC. 1860D–5. (a) DISSEMINATION OF INFORMA-*
 20 *TION.—*

21 “(1) *GENERAL INFORMATION.—An eligible entity*
 22 *offering a Medicare Prescription Drug plan shall dis-*
 23 *close, in a clear, accurate, and standardized form to*
 24 *each enrollee at the time of enrollment, and at least*
 25 *annually thereafter, the information described in sec-*

1 *tion 1852(c)(1) relating to such plan. Such informa-*
 2 *tion includes the following:*

3 *“(A) Access to covered drugs, including ac-*
 4 *cess through pharmacy networks.*

5 *“(B) How any formulary used by the entity*
 6 *functions.*

7 *“(C) Copayments, coinsurance, and deduct-*
 8 *ible requirements.*

9 *“(D) Grievance and appeals processes.*

10 *The information described in the preceding sentence*
 11 *shall also be made available on request to prospective*
 12 *enrollees during open enrollment periods.*

13 *“(2) DISCLOSURE UPON REQUEST OF GENERAL*
 14 *COVERAGE, UTILIZATION, AND GRIEVANCE INFORMA-*
 15 *TION.—Upon request of an individual eligible to en-*
 16 *roll in a Medicare Prescription Drug plan, the eligi-*
 17 *ble entity offering such plan shall provide informa-*
 18 *tion similar (as determined by the Administrator) to*
 19 *the information described in subparagraphs (A), (B),*
 20 *and (C) of section 1852(c)(2) to such individual.*

21 *“(3) RESPONSE TO BENEFICIARY QUESTIONS.—*
 22 *An eligible entity offering a Medicare Prescription*
 23 *Drug plan shall have a mechanism for providing on*
 24 *a timely basis specific information to enrollees upon*

1 *request, including information on the coverage of spe-*
 2 *cific drugs and changes in its formulary.*

3 “(4) *CLAIMS INFORMATION.—An eligible entity*
 4 *offering a Medicare Prescription Drug plan must fur-*
 5 *nish to enrolled individuals in a form easily under-*
 6 *standable to such individuals—*

7 “(A) *an explanation of benefits (in accord-*
 8 *ance with section 1806(a) or in a comparable*
 9 *manner); and*

10 “(B) *when prescription drug benefits are*
 11 *provided under this part, a notice of the benefits*
 12 *in relation to the initial coverage limit and an-*
 13 *ual out-of-pocket limit for the current year (ex-*
 14 *cept that such notice need not be provided more*
 15 *often than monthly).*

16 “(5) *APPROVAL OF MARKETING MATERIAL AND*
 17 *APPLICATION FORMS.—The provisions of section*
 18 *1851(h) shall apply to marketing material and appli-*
 19 *cation forms under this part in the same manner as*
 20 *such provisions apply to marketing material and ap-*
 21 *plication forms under part C.*

22 “(b) *ACCESS TO COVERED DRUGS.—*

23 “(1) *ACCESS TO NEGOTIATED PRICES FOR PRE-*
 24 *SCRIPTION DRUGS.—An eligible entity offering a*
 25 *Medicare Prescription Drug plan shall have in place*

1 *procedures to ensure that beneficiaries are not charged*
 2 *more than the negotiated price of a covered drug.*
 3 *Such procedures shall include the issuance of a card*
 4 *(or other technology) that may be used by an enrolled*
 5 *beneficiary for the purchase of prescription drugs for*
 6 *which coverage is not otherwise provided under the*
 7 *Medicare Prescription Drug plan.*

8 “(2) ASSURING PHARMACY ACCESS.—

9 “(A) IN GENERAL.—An eligible entity offer-
 10 *ing a Medicare Prescription Drug plan shall se-*
 11 *cure the participation in its network of a suffi-*
 12 *cient number of pharmacies that dispense (other*
 13 *than by mail order) drugs directly to patients to*
 14 *ensure convenient access (as determined by the*
 15 *Administrator and including adequate emer-*
 16 *gency access) for enrolled beneficiaries, in ac-*
 17 *cordance with standards established by the Ad-*
 18 *ministrator under section 1860D–7(g) that en-*
 19 *sure such convenient access. Such standards shall*
 20 *take into account reasonable distances to phar-*
 21 *macy services in urban and rural areas and ac-*
 22 *cess to pharmacy services of the Indian Health*
 23 *Service and Indian tribes and tribal organiza-*
 24 *tions.*

1 “(B) *USE OF POINT-OF-SERVICE SYSTEM.*—

2 *An eligible entity offering a Medicare Prescrip-*
 3 *tion Drug plan shall establish an optional point-*
 4 *of-service method of operation under which—*

5 “(i) *the plan provides access to any or*
 6 *all pharmacies that are not participating*
 7 *pharmacies in its network; and*

8 “(ii) *the plan may charge beneficiaries*
 9 *through adjustments in copayments any ad-*
 10 *ditional costs associated with the point-of-*
 11 *service option.*

12 *The additional copayments so charged shall not*
 13 *count toward the application of section 1860D–*
 14 *6(c).*

15 “(C) *LEVEL PLAYING FIELD.*—*An eligible*
 16 *entity offering a Medicare Prescription Drug*
 17 *plan shall permit enrollees to receive benefits*
 18 *(which may include a 90-day supply of drugs or*
 19 *biologicals) through a community pharmacy,*
 20 *rather than through mail order, and may permit*
 21 *a differential amount to be paid by such enroll-*
 22 *ees.*

23 “(3) *REQUIREMENTS ON DEVELOPMENT AND AP-*
 24 *PLICATION OF FORMULARIES.*—*If an eligible entity of-*

1 *fering a Medicare Prescription Drug plan uses a for-*
 2 *mulary, the following requirements must be met:*

3 *“(A) PHARMACY AND THERAPEUTIC (P&T)*
 4 *COMMITTEE.—*

5 *“(i) IN GENERAL.—The eligible entity*
 6 *must establish a pharmacy and therapeutic*
 7 *committee that develops and reviews the for-*
 8 *mulary.*

9 *“(ii) COMPOSITION.—A pharmacy and*
 10 *therapeutic committee shall include at least*
 11 *1 academic expert, at least 1 practicing*
 12 *physician, and at least 1 practicing phar-*
 13 *macist, all of whom have expertise in the*
 14 *care of elderly or disabled persons, and a*
 15 *majority of the members of such committee*
 16 *shall consist of individuals who are a prac-*
 17 *ticing physician or a practicing pharmacist*
 18 *(or both).*

19 *“(B) FORMULARY DEVELOPMENT.—In de-*
 20 *veloping and reviewing the formulary, the com-*
 21 *mittee shall base clinical decisions on the*
 22 *strength of scientific evidence and standards of*
 23 *practice, including assessing peer-reviewed med-*
 24 *ical literature, such as randomized clinical*
 25 *trials, pharmacoeconomic studies, outcomes re-*

1 *search data, and on such other information as*
 2 *the committee determines to be appropriate.*

3 “(C) *INCLUSION OF DRUGS IN ALL THERA-*
 4 *PEUTIC CATEGORIES AND CLASSES.—*

5 “(i) *IN GENERAL.—The formulary*
 6 *must include drugs within each therapeutic*
 7 *category and class of covered drugs (as de-*
 8 *finied by the Administrator), although not*
 9 *necessarily for all drugs within such cat-*
 10 *egories and classes.*

11 “(ii) *REQUIREMENT.—In defining*
 12 *therapeutic categories and classes of covered*
 13 *drugs pursuant to clause (i), the Adminis-*
 14 *trator shall use—*

15 “(I) *the compendia referred to sec-*
 16 *tion 1927(g)(1)(B)(i); and*

17 “(II) *other recognized sources of*
 18 *drug classifications and categorizations*
 19 *determined appropriate by the Admin-*
 20 *istrator.*

21 “(D) *PROVIDER EDUCATION.—The com-*
 22 *mittee shall establish policies and procedures to*
 23 *educate and inform health care providers con-*
 24 *cerning the formulary.*

1 “(E) NOTICE BEFORE REMOVING DRUGS
 2 FROM FORMULARY.—Any removal of a drug from
 3 a formulary shall take effect only after appro-
 4 priate notice is made available to beneficiaries,
 5 physicians, and pharmacists.

6 “(F) APPEALS AND EXCEPTIONS TO APPLI-
 7 CATION.—The eligible entity must have, as part
 8 of the appeals process under subsection (e), a
 9 process for timely appeals for denials of coverage
 10 based on such application of the formulary.

11 “(c) COST AND UTILIZATION MANAGEMENT; QUALITY
 12 ASSURANCE; MEDICATION THERAPY MANAGEMENT PRO-
 13 GRAM.—

14 “(1) IN GENERAL.—An eligible entity shall have
 15 in place the following with respect to covered drugs:

16 “(A) A cost-effective drug utilization man-
 17 agement program, including incentives to reduce
 18 costs when appropriate.

19 “(B) Quality assurance measures to reduce
 20 medical errors and adverse drug interactions
 21 and to improve medication use, which—

22 “(i) shall include a medication therapy
 23 management program described in para-
 24 graph (2); and

1 “(ii) may include beneficiary edu-
 2 cation programs, counseling, medication re-
 3 fill reminders, and special packaging.

4 “(C) A program to control fraud, abuse,
 5 and waste.

6 *Nothing in this section shall be construed as impair-*
 7 *ing an eligible entity from applying cost management*
 8 *tools (including differential payments) under all*
 9 *methods of operation.*

10 “(2) *MEDICATION THERAPY MANAGEMENT PRO-*
 11 *GRAM.—*

12 “(A) *IN GENERAL.—A medication therapy*
 13 *management program described in this para-*
 14 *graph is a program of drug therapy management*
 15 *and medication administration that is designed*
 16 *to assure, with respect to beneficiaries with*
 17 *chronic diseases (such as diabetes, asthma, hy-*
 18 *pertension, hyperlipidemia, and congestive heart*
 19 *failure) or multiple prescriptions, that covered*
 20 *drugs under the Medicare Prescription Drug*
 21 *plan are appropriately used to optimize thera-*
 22 *peutic outcomes through improved medication*
 23 *use and to achieve therapeutic goals and reduce*
 24 *the risk of adverse events, including adverse drug*
 25 *interactions.*

1 “(B) *ELEMENTS.—Such program may*
 2 *include—*

3 “(i) *enhanced beneficiary under-*
 4 *standing of such appropriate use through*
 5 *beneficiary education, counseling, and other*
 6 *appropriate means;*

7 “(ii) *increased beneficiary adherence*
 8 *with prescription medication regimens*
 9 *through medication refill reminders, special*
 10 *packaging, and other appropriate means;*
 11 *and*

12 “(iii) *detection of patterns of overuse*
 13 *and underuse of prescription drugs.*

14 “(C) *DEVELOPMENT OF PROGRAM IN CO-*
 15 *OPERATION WITH LICENSED PHARMACISTS.—The*
 16 *program shall be developed in cooperation with*
 17 *licensed and practicing pharmacists and physi-*
 18 *cians.*

19 “(D) *CONSIDERATIONS IN PHARMACY*
 20 *FEES.—The eligible entity offering a Medicare*
 21 *Prescription Drug plan shall take into account,*
 22 *in establishing fees for pharmacists and others*
 23 *providing services under the medication therapy*
 24 *management program, the resources and time*
 25 *used in implementing the program.*

1 “(3) *PUBLIC DISCLOSURE OF PHARMACEUTICAL*
2 *PRICES FOR EQUIVALENT DRUGS.*—*The eligible entity*
3 *offering a Medicare Prescription Drug plan shall pro-*
4 *vide that each pharmacy or other dispenser that ar-*
5 *ranges for the dispensing of a covered drug shall in-*
6 *form the beneficiary at the time of purchase of the*
7 *drug of any differential between the price of the pre-*
8 *scribed drug to the enrollee and the price of the lowest*
9 *cost generic drug covered under the plan that is thera-*
10 *peutically equivalent and bioequivalent.*

11 “(d) *GRIEVANCE MECHANISM, COVERAGE DETERMINA-*
12 *TIONS, AND RECONSIDERATIONS.*—

13 “(1) *IN GENERAL.*—*An eligible entity shall pro-*
14 *vide meaningful procedures for hearing and resolving*
15 *grievances between the eligible entity (including any*
16 *entity or individual through which the eligible entity*
17 *provides covered benefits) and enrollees with Medicare*
18 *Prescription Drug plans of the eligible entity under*
19 *this part in accordance with section 1852(f).*

20 “(2) *APPLICATION OF COVERAGE DETERMINA-*
21 *TION AND RECONSIDERATION PROVISIONS.*—*The re-*
22 *quirements of paragraphs (1) through (3) of section*
23 *1852(g) shall apply to an eligible entity with respect*
24 *to covered benefits under the Medicare Prescription*
25 *Drug plan it offers under this part in the same man-*

1 *ner as such requirements apply to a*
 2 *MedicareAdvantage organization with respect to bene-*
 3 *fits it offers under a MedicareAdvantage plan under*
 4 *part C.*

5 *“(3) REQUEST FOR REVIEW OF TIERED FOR-*
 6 *MULARY DETERMINATIONS.—In the case of a Medicare*
 7 *Prescription Drug plan offered by an eligible entity*
 8 *that provides for tiered cost-sharing for drugs in-*
 9 *cluded within a formulary and provides lower cost-*
 10 *sharing for preferred drugs included within the for-*
 11 *mulary, an individual who is enrolled in the plan*
 12 *may request coverage of a nonpreferred drug under*
 13 *the terms applicable for preferred drugs if the pre-*
 14 *scribing physician determines that the preferred drug*
 15 *for treatment of the same condition is not as effective*
 16 *for the individual or has adverse effects for the indi-*
 17 *vidual.*

18 *“(e) APPEALS.—*

19 *“(1) IN GENERAL.—Subject to paragraph (2), the*
 20 *requirements of paragraphs (4) and (5) of section*
 21 *1852(g) shall apply to an eligible entity with respect*
 22 *to drugs not included on any formulary in a manner*
 23 *that is similar (as determined by the Administrator)*
 24 *to the manner that such requirements apply to a*
 25 *MedicareAdvantage organization with respect to bene-*

1 *fits it offers under a MedicareAdvantage plan under*
 2 *part C.*

3 “(2) *FORMULARY DETERMINATIONS.—An indi-*
 4 *vidual who is enrolled in a Medicare Prescription*
 5 *Drug plan offered by an eligible entity may appeal*
 6 *to obtain coverage for a covered drug that is not on*
 7 *a formulary of the entity under the terms applicable*
 8 *for a formulary drug if the prescribing physician de-*
 9 *termines that the formulary drug for treatment of the*
 10 *same condition is not as effective for the individual*
 11 *or has adverse effects for the individual.*

12 “(f) *PRIVACY, CONFIDENTIALITY, AND ACCURACY OF*
 13 *ENROLLEE RECORDS.—Insofar as an eligible entity main-*
 14 *tains individually identifiable medical records or other*
 15 *health information regarding eligible beneficiaries enrolled*
 16 *in the Medicare Prescription Drug plan offered by the enti-*
 17 *ty, the entity shall have in place procedures to—*

18 “(1) *safeguard the privacy of any individually*
 19 *identifiable beneficiary information in a manner con-*
 20 *sistent with the Federal regulations (concerning the*
 21 *privacy of individually identifiable health informa-*
 22 *tion) promulgated under section 264(c) of the Health*
 23 *Insurance Portability and Accountability Act of 1996;*

24 “(2) *maintain such records and information in*
 25 *a manner that is accurate and timely;*

1 “(3) ensure timely access by such beneficiaries to
2 such records and information; and

3 “(4) otherwise comply with applicable laws re-
4 lating to patient privacy and confidentiality.

5 “(g) *UNIFORM MONTHLY PLAN PREMIUM.*—An eligible
6 entity shall ensure that the monthly plan premium for a
7 Medicare Prescription Drug plan charged under this part
8 is the same for all eligible beneficiaries enrolled in the plan.
9 Such requirement shall not apply to enrollees of a Medicare
10 Prescription Drug plan who are enrolled in the plan pursu-
11 ant to a contractual agreement between the plan and an
12 employer or other group health plan that provides employ-
13 ment-based retiree health coverage (as defined in section
14 1860D–20(d)(4)(B)) if the premium amount is the same for
15 all such enrollees under such agreement.

16 “(h) *CONSUMER SATISFACTION SURVEYS.*—An eligible
17 entity shall conduct consumer satisfaction surveys with re-
18 spect to the plan and the entity. The Administrator shall
19 establish uniform requirements for such surveys.

20 “*PRESCRIPTION DRUG BENEFITS*

21 “*SEC. 1860D–6. (a) REQUIREMENTS.*—

22 “(1) *IN GENERAL.*—For purposes of this part
23 and part C, the term ‘qualified prescription drug cov-
24 erage’ means either of the following:

25 “(A) *STANDARD PRESCRIPTION DRUG COV-*
26 *ERAGE WITH ACCESS TO NEGOTIATED PRICES.*—

Standard prescription drug coverage (as defined in subsection (c)) and access to negotiated prices under subsection (e).

“(B) *ACTUARIALLY EQUIVALENT PRESCRIPTION DRUG COVERAGE WITH ACCESS TO NEGOTIATED PRICES.*—Coverage of covered drugs which meets the alternative coverage requirements of subsection (d) and access to negotiated prices under subsection (e), but only if it is approved by the Administrator as provided under subsection (d).

“(2) *PERMITTING ADDITIONAL PRESCRIPTION DRUG COVERAGE.*—

“(A) *IN GENERAL.*—Subject to subparagraph (B) and section 1860D–13(c)(2), nothing in this part shall be construed as preventing qualified prescription drug coverage from including coverage of covered drugs that exceeds the coverage required under paragraph (1).

“(B) *REQUIREMENT.*—An eligible entity may not offer a Medicare Prescription Drug plan that provides additional benefits pursuant to subparagraph (A) in an area unless the eligible entity offering such plan also offers a Medicare Prescription Drug plan in the area that

1 *only provides the coverage of prescription drugs*
 2 *that is required under paragraph (1).*

3 “(3) *COST CONTROL MECHANISMS.—In pro-*
 4 *viding qualified prescription drug coverage, the entity*
 5 *offering the Medicare Prescription Drug plan or the*
 6 *MedicareAdvantage plan may use a variety of cost*
 7 *control mechanisms, including the use of formularies,*
 8 *tiered copayments, selective contracting with pro-*
 9 *viders of prescription drugs, and mail order phar-*
 10 *macies.*

11 “(b) *APPLICATION OF SECONDARY PAYOR PROVI-*
 12 *SIONS.—The provisions of section 1852(a)(4) shall apply*
 13 *under this part in the same manner as they apply under*
 14 *part C.*

15 “(c) *STANDARD PRESCRIPTION DRUG COVERAGE.—*
 16 *For purposes of this part and part C, the term ‘standard*
 17 *prescription drug coverage’ means coverage of covered drugs*
 18 *that meets the following requirements:*

19 “(1) *DEDUCTIBLE.—*

20 “(A) *IN GENERAL.—The coverage has an*
 21 *annual deductible—*

22 “(i) *for 2006, that is equal to \$275; or*

23 “(ii) *for a subsequent year, that is*
 24 *equal to the amount specified under this*
 25 *paragraph for the previous year increased*

1 *by the percentage specified in paragraph (5)*
 2 *for the year involved.*

3 “(B) *ROUNDING.*—*Any amount determined*
 4 *under subparagraph (A)(ii) that is not a mul-*
 5 *tiple of \$1 shall be rounded to the nearest mul-*
 6 *tiple of \$1.*

7 “(2) *LIMITS ON COST-SHARING.*—*The coverage*
 8 *has cost-sharing (for costs above the annual deductible*
 9 *specified in paragraph (1) and up to the initial cov-*
 10 *erage limit under paragraph (3)) that is equal to 50*
 11 *percent or that is actuarially consistent (using proc-*
 12 *esses established under subsection (f)) with an average*
 13 *expected payment of 50 percent of such costs.*

14 “(3) *INITIAL COVERAGE LIMIT.*—

15 “(A) *IN GENERAL.*—*Subject to paragraph*
 16 *(4), the coverage has an initial coverage limit on*
 17 *the maximum costs that may be recognized for*
 18 *payment purposes (including the annual deduct-*
 19 *ible)—*

20 “(i) *for 2006, that is equal to \$4,500;*

21 *or*

22 “(ii) *for a subsequent year, that is*
 23 *equal to the amount specified in this para-*
 24 *graph for the previous year, increased by*

1 the annual percentage increase described in
2 paragraph (5) for the year involved.

3 “(B) *ROUNDING.*—Any amount determined
4 under subparagraph (A)(ii) that is not a mul-
5 tiple of \$1 shall be rounded to the nearest mul-
6 tiple of \$1.

7 “(4) *LIMITATION ON OUT-OF-POCKET EXPENDI-*
8 *TURES BY BENEFICIARY.*—

9 “(A) *IN GENERAL.*—The coverage provides
10 benefits with cost-sharing that is equal to 10 per-
11 cent after the individual has incurred costs (as
12 described in subparagraph (C)) for covered drugs
13 in a year equal to the annual out-of-pocket limit
14 specified in subparagraph (B).

15 “(B) *ANNUAL OUT-OF-POCKET LIMIT.*—

16 “(i) *IN GENERAL.*—For purposes of
17 this part, the ‘annual out-of-pocket limit’
18 specified in this subparagraph—

19 “(I) for 2006, is equal to \$3,700;

20 or

21 “(II) for a subsequent year, is
22 equal to the amount specified in this
23 subparagraph for the previous year,
24 increased by the annual percentage in-

1 crease described in paragraph (5) for
2 the year involved.

3 “(ii) *ROUNDING*.—Any amount deter-
4 mined under clause (i)(II) that is not a
5 multiple of \$1 shall be rounded to the near-
6 est multiple of \$1.

7 “(C) *APPLICATION*.—In applying subpara-
8 graph (A)—

9 “(i) incurred costs shall only include
10 costs incurred, with respect to covered
11 drugs, for the annual deductible (described
12 in paragraph (1)), cost-sharing (described
13 in paragraph (2)), and amounts for which
14 benefits are not provided because of the ap-
15 plication of the initial coverage limit de-
16 scribed in paragraph (3) (including costs
17 incurred for covered drugs described in sec-
18 tion 1860D(a)(2)(C)); and

19 “(ii) such costs shall be treated as in-
20 curred only if they are paid by the indi-
21 vidual (or by another individual, such as a
22 family member, on behalf of the individual),
23 under section 1860D–19 (but only with re-
24 spect to the percentage of such costs that the
25 individual is responsible for under that sec-

tion), under title XIX, or under a State pharmaceutical assistance program and the individual (or other individual) is not reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement for such costs.

“(D) INFORMATION REGARDING THIRD-PARTY REIMBURSEMENT.—In order to ensure compliance with the requirements of subparagraph (C)(ii), the Administrator is authorized to establish procedures, in coordination with the Secretary of Treasury and the Secretary of Labor, for determining whether costs for individuals are being reimbursed through insurance or otherwise, a group health plan, or other third-party payment arrangement, and for alerting the entities in which such individuals are enrolled about such reimbursement arrangements. An entity with a contract under this part may also periodically ask individuals enrolled in a plan offered by the entity whether the individuals have or expect to receive such third-party reimbursement. A material misrepresentation of the information described in the preceding sentence by an individual (as defined in standards

1 *set by the Administrator and determined through*
 2 *a process established by the Administrator) shall*
 3 *constitute grounds for termination of enrollment*
 4 *under section 1860D–2(d).*

5 “(5) *ANNUAL PERCENTAGE INCREASE.*—*For pur-*
 6 *poses of this part, the annual percentage increase*
 7 *specified in this paragraph for a year is equal to the*
 8 *annual percentage increase in average per capita ag-*
 9 *gregate expenditures for covered drugs in the United*
 10 *States for beneficiaries under this title, as determined*
 11 *by the Administrator for the 12-month period ending*
 12 *in July of the previous year.*

13 “(d) *ALTERNATIVE COVERAGE REQUIREMENTS.*—*A*
 14 *Medicare Prescription Drug plan or Medicare Advantage*
 15 *plan may provide a different prescription drug benefit de-*
 16 *sign from the standard prescription drug coverage described*
 17 *in subsection (c) so long as the Administrator determines*
 18 *(based on an actuarial analysis by the Administrator) that*
 19 *the following requirements are met and the plan applies*
 20 *for, and receives, the approval of the Administrator for such*
 21 *benefit design:*

22 “(1) *ASSURING AT LEAST ACTUARIALLY EQUIVA-*
 23 *LENT PRESCRIPTION DRUG COVERAGE.*—

24 “(A) *ASSURING EQUIVALENT VALUE OF*
 25 *TOTAL COVERAGE.*—*The actuarial value of the*

total coverage (as determined under subsection (f)) is at least equal to the actuarial value (as so determined) of standard prescription drug coverage.

“(B) ASSURING EQUIVALENT UNSUBSIDIZED VALUE OF COVERAGE.—The unsubsidized value of the coverage is at least equal to the unsubsidized value of standard prescription drug coverage. For purposes of this subparagraph, the unsubsidized value of coverage is the amount by which the actuarial value of the coverage (as determined under subsection (f)) exceeds the actuarial value of the amounts associated with the application of section 1860D–17(c) and reinsurance payments under section 1860D–20 with respect to such coverage.

“(C) ASSURING STANDARD PAYMENT FOR COSTS AT INITIAL COVERAGE LIMIT.—The coverage is designed, based upon an actuarially representative pattern of utilization (as determined under subsection (f)), to provide for the payment, with respect to costs incurred that are equal to the initial coverage limit under subsection (c)(3), of an amount equal to at least the product of—

1 “(i) *such initial coverage limit minus*
 2 *the deductible under subsection (c)(1); and*
 3 “(ii) *the percentage specified in sub-*
 4 *section (c)(2).*

5 *Benefits other than qualified prescription drug cov-*
 6 *erage shall not be taken into account for purposes of*
 7 *this paragraph.*

8 “(2) *DEDUCTIBLE AND LIMITATION ON OUT-OF-*
 9 *POCKET EXPENDITURES BY BENEFICIARIES MAY NOT*
 10 *VARY.—The coverage may not vary the deductible*
 11 *under subsection (c)(1) for the year or the limitation*
 12 *on out-of-pocket expenditures by beneficiaries de-*
 13 *scribed in subsection (c)(4) for the year.*

14 “(e) *ACCESS TO NEGOTIATED PRICES.—*

15 “(1) *ACCESS.—*

16 “(A) *IN GENERAL.—Under qualified pre-*
 17 *scription drug coverage offered by an eligible en-*
 18 *tity or a MedicareAdvantage organization, the*
 19 *entity or organization shall provide beneficiaries*
 20 *with access to negotiated prices used for payment*
 21 *for covered drugs, regardless of the fact that no*
 22 *benefits may be payable under the coverage with*
 23 *respect to such drugs because of the application*
 24 *of the deductible, any cost-sharing, or an initial*
 25 *coverage limit (described in subsection (c)(3)).*

1 *For purposes of this part, the term ‘negotiated*
 2 *prices’ includes all discounts, direct or indirect*
 3 *subsidies, rebates, or other price concessions or*
 4 *direct or indirect remunerations.*

5 *“(B) MEDICAID RELATED PROVISIONS.—In-*
 6 *sofar as a State elects to provide medical assist-*
 7 *ance under title XIX for a drug based on the*
 8 *prices negotiated under a Medicare Prescription*
 9 *Drug plan under this part—*

10 *“(i) the medical assistance for such a*
 11 *drug shall be disregarded for purposes of a*
 12 *rebate agreement entered into under section*
 13 *1927 which would otherwise apply to the*
 14 *provision of medical assistance for the drug*
 15 *under title XIX; and*

16 *“(ii) the prices negotiated under a*
 17 *Medicare Prescription Drug plan with re-*
 18 *spect to covered drugs, under a*
 19 *MedicareAdvantage plan with respect to*
 20 *such drugs, or under a qualified retiree pre-*
 21 *scription drug plan (as defined in section*
 22 *1860D–20(e)(4)) with respect to such drugs,*
 23 *on behalf of eligible beneficiaries, shall (not-*
 24 *withstanding any other provision of law)*
 25 *not be taken into account for the purposes*

1 *of establishing the best price under section*
 2 *1927(c)(1)(C).*

3 “(2) *CARDS OR OTHER TECHNOLOGY.*—

4 “(A) *IN GENERAL.*—*In providing the access*
 5 *under paragraph (1), the eligible entity or*
 6 *MedicareAdvantage organization shall issue a*
 7 *card or use other technology pursuant to section*
 8 *1860D–5(b)(1).*

9 “(B) *NATIONAL STANDARDS.*—

10 “(i) *DEVELOPMENT.*—*The Adminis-*
 11 *trator shall provide for the development of*
 12 *national standards relating to a standard-*
 13 *ized format for the card or other technology*
 14 *required under subparagraph (A). Such*
 15 *standards shall be compatible with parts C*
 16 *and D of title XI and may be based on*
 17 *standards developed by an appropriate*
 18 *standard setting organization.*

19 “(ii) *CONSULTATION.*—*In developing*
 20 *the standards under clause (i), the Adminis-*
 21 *trator shall consult with the National Coun-*
 22 *cil for Prescription Drug Programs and*
 23 *other standard-setting organizations deter-*
 24 *mined appropriate by the Administrator.*

1 “(iii) *IMPLEMENTATION.*—*The Admin-*
2 *istrator shall implement the standards de-*
3 *veloped under clause (i) by January 1,*
4 *2008.*

5 “(3) *DISCLOSURE.*—*The eligible entity offering a*
6 *Medicare Prescription Drug plan and the*
7 *MedicareAdvantage organization offering a*
8 *MedicareAdvantage plan shall disclose to the Admin-*
9 *istrator (in a manner specified by the Administrator)*
10 *the extent to which discounts, direct or indirect sub-*
11 *sidies, rebates, or other price concessions or direct or*
12 *indirect remunerations made available to the entity*
13 *or organization by a manufacturer are passed*
14 *through to enrollees through pharmacies and other*
15 *dispensers or otherwise. The provisions of section*
16 *1927(b)(3)(D) shall apply to information disclosed to*
17 *the Administrator under this paragraph in the same*
18 *manner as such provisions apply to information dis-*
19 *closed under such section.*

20 “(4) *AUDITS AND REPORTS.*—*To protect against*
21 *fraud and abuse and to ensure proper disclosures and*
22 *accounting under this part, in addition to any pro-*
23 *tections against fraud and abuse provided under sec-*
24 *tion 1860D–7(f)(1), the Administrator may periodi-*
25 *cally audit the financial statements and records of an*

1 *eligible entity offering a Medicare Prescription Drug*
 2 *plan and a MedicareAdvantage organization offering*
 3 *a MedicareAdvantage plan with the auditor of the*
 4 *Administrator’s choice.*

5 “(f) *ACTUARIAL VALUATION; DETERMINATION OF AN-*
 6 *NUAL PERCENTAGE INCREASES.—*

7 “(1) *PROCESSES.—For purposes of this section,*
 8 *the Administrator shall establish processes and*
 9 *methods—*

10 “(A) *for determining the actuarial valu-*
 11 *ation of prescription drug coverage, including—*

12 “(i) *an actuarial valuation of standard*
 13 *prescription drug coverage and of the rein-*
 14 *surance payments under section 1860D–20;*

15 “(ii) *the use of generally accepted actu-*
 16 *arial principles and methodologies; and*

17 “(iii) *applying the same methodology*
 18 *for determinations of alternative coverage*
 19 *under subsection (d) as is used with respect*
 20 *to determinations of standard prescription*
 21 *drug coverage under subsection (c); and*

22 “(B) *for determining annual percentage in-*
 23 *creases described in subsection (c)(5).*

24 *Such processes shall take into account any effect that*
 25 *providing actuarially equivalent prescription drug*

1 *coverage rather than standard prescription drug cov-*
 2 *erage has on drug utilization.*

3 “(2) *USE OF OUTSIDE ACTUARIES.*—*Under the*
 4 *processes under paragraph (1)(A), eligible entities*
 5 *and MedicareAdvantage organizations may use actu-*
 6 *arial opinions certified by independent, qualified ac-*
 7 *tuaries to establish actuarial values, but the Adminis-*
 8 *trator shall determine whether such actuarial values*
 9 *meet the requirements under subsection (c)(1).*

10 “*REQUIREMENTS FOR ENTITIES OFFERING MEDICARE PRE-*
 11 *SCRIPTION DRUG PLANS; ESTABLISHMENT OF STAND-*
 12 *ARDS*

13 “*SEC. 1860D–7. (a) GENERAL REQUIREMENTS.*—*An*
 14 *eligible entity offering a Medicare Prescription Drug plan*
 15 *shall meet the following requirements:*

16 “(1) *LICENSURE.*—*Subject to subsection (c), the*
 17 *entity is organized and licensed under State law as*
 18 *a risk-bearing entity eligible to offer health insurance*
 19 *or health benefits coverage in each State in which it*
 20 *offers a Medicare Prescription Drug plan.*

21 “(2) *ASSUMPTION OF FINANCIAL RISK.*—

22 “(A) *IN GENERAL.*—*Subject to subpara-*
 23 *graph (B) and subsections (d)(2) and (e) of sec-*
 24 *tion 1860D–13, to the extent that the entity is at*
 25 *risk pursuant to such section 1860D–16, the en-*
 26 *tity assumes financial risk on a prospective basis*

1 *for the benefits that it offers under a Medicare*
 2 *Prescription Drug plan and that is not covered*
 3 *under section 1860D–20.*

4 “(B) *REINSURANCE PERMITTED.*—*To the*
 5 *extent that the entity is at risk pursuant to sec-*
 6 *tion 1860D–16, the entity may obtain insurance*
 7 *or make other arrangements for the cost of cov-*
 8 *erage provided to any enrolled member under*
 9 *this part.*

10 “(3) *SOLVENCY FOR UNLICENSED ENTITIES.*—*In*
 11 *the case of an eligible entity that is not described in*
 12 *paragraph (1) and for which a waiver has been ap-*
 13 *proved under subsection (c), such entity shall meet*
 14 *solvency standards established by the Administrator*
 15 *under subsection (d).*

16 “(b) *CONTRACT REQUIREMENTS.*—*The Administrator*
 17 *shall not permit an eligible beneficiary to elect a Medicare*
 18 *Prescription Drug plan offered by an eligible entity under*
 19 *this part, and the entity shall not be eligible for payments*
 20 *under section 1860D–16 or 1860D–20, unless the Adminis-*
 21 *trator has entered into a contract under this subsection with*
 22 *the entity with respect to the offering of such plan. Such*
 23 *a contract with an entity may cover more than 1 Medicare*
 24 *Prescription Drug plan. Such contract shall provide that*
 25 *the entity agrees to comply with the applicable requirements*

1 *and standards of this part and the terms and conditions*
 2 *of payment as provided for in this part.*

3 “(c) *WAIVER OF CERTAIN REQUIREMENTS IN ORDER*
 4 *TO ENSURE BENEFICIARY CHOICE.*—

5 “(1) *IN GENERAL.*—*In the case of an eligible en-*
 6 *tity that seeks to offer a Medicare Prescription Drug*
 7 *plan in a State, the Administrator shall waive the re-*
 8 *quirement of subsection (a)(1) that the entity be li-*
 9 *censed in that State if the Administrator determines,*
 10 *based on the application and other evidence presented*
 11 *to the Administrator, that any of the grounds for ap-*
 12 *proval of the application described in paragraph (2)*
 13 *have been met.*

14 “(2) *GROUND FOR APPROVAL.*—*The grounds for*
 15 *approval under this paragraph are the grounds for*
 16 *approval described in subparagraphs (B), (C), and*
 17 *(D) of section 1855(a)(2), and also include the appli-*
 18 *cation by a State of any grounds other than those re-*
 19 *quired under Federal law.*

20 “(3) *APPLICATION OF WAIVER PROCEDURES.*—
 21 *With respect to an application for a waiver (or a*
 22 *waiver granted) under this subsection, the provisions*
 23 *of subparagraphs (E), (F), and (G) of section*
 24 *1855(a)(2) shall apply.*

1 “(4) *REFERENCES TO CERTAIN PROVISIONS.—*
 2 *For purposes of this subsection, in applying the pro-*
 3 *visions of section 1855(a)(2) under this subsection to*
 4 *Medicare Prescription Drug plans and eligible*
 5 *entities—*

6 “(A) *any reference to a waiver application*
 7 *under section 1855 shall be treated as a reference*
 8 *to a waiver application under paragraph (1);*
 9 *and*

10 “(B) *any reference to solvency standards*
 11 *were treated as a reference to solvency standards*
 12 *established under subsection (d).*

13 “(d) *SOLVENCY STANDARDS FOR NON-LICENSED ENTI-*
 14 *TIES.—*

15 “(1) *ESTABLISHMENT AND PUBLICATION.—The*
 16 *Administrator, in consultation with the National As-*
 17 *sociation of Insurance Commissioners, shall establish*
 18 *and publish, by not later than January 1, 2005, fi-*
 19 *nancial solvency and capital adequacy standards for*
 20 *entities described in paragraph (2).*

21 “(2) *COMPLIANCE WITH STANDARDS.—An eligi-*
 22 *ble entity that is not licensed by a State under sub-*
 23 *section (a)(1) and for which a waiver application has*
 24 *been approved under subsection (c) shall meet sol-*
 25 *vency and capital adequacy standards established*

1 under paragraph (1). The Administrator shall estab-
 2 lish certification procedures for such eligible entities
 3 with respect to such solvency standards in the manner
 4 described in section 1855(c)(2).

5 “(e) *LICENSURE DOES NOT SUBSTITUTE FOR OR CON-*
 6 *STITUTE CERTIFICATION.*—The fact that an entity is li-
 7 censed in accordance with subsection (a)(1) or has a waiver
 8 application approved under subsection (c) does not deem
 9 the eligible entity to meet other requirements imposed under
 10 this part for an eligible entity.

11 “(f) *INCORPORATION OF CERTAIN*
 12 *MEDICAREADVANTAGE CONTRACT REQUIREMENTS.*—The
 13 following provisions of section 1857 shall apply, subject to
 14 subsection (c)(4), to contracts under this section in the same
 15 manner as they apply to contracts under section 1857(a):

16 “(1) *PROTECTIONS AGAINST FRAUD AND BENE-*
 17 *FIICIARY PROTECTIONS.*—Section 1857(d).

18 “(2) *INTERMEDIATE SANCTIONS.*—Section
 19 1857(g), except that in applying such section—

20 “(A) the reference in section 1857(g)(1)(B)
 21 to section 1854 is deemed a reference to this
 22 part; and

23 “(B) the reference in section 1857(g)(1)(F)
 24 to section 1852(k)(2)(A)(ii) shall not be applied.

1 “(3) *PROCEDURES FOR TERMINATION.*—Section
2 1857(h).

3 “(g) *OTHER STANDARDS.*—The Administrator shall
4 establish by regulation other standards (not described in
5 subsection (d)) for eligible entities and Medicare Prescrip-
6 tion Drug plans consistent with, and to carry out, this part.
7 The Administrator shall publish such regulations by Janu-
8 ary 1, 2005.

9 “(h) *PERIODIC REVIEW AND REVISION OF STAND-*
10 *ARDS.*—

11 “(1) *IN GENERAL.*—Subject to paragraph (2), the
12 Administrator shall periodically review the standards
13 established under this section and, based on such re-
14 view, may revise such standards if the Administrator
15 determines such revision to be appropriate.

16 “(2) *PROHIBITION OF MIDYEAR IMPLEMENTA-*
17 *TION OF SIGNIFICANT NEW REGULATORY REQUIRE-*
18 *MENTS.*—The Administrator may not implement,
19 other than at the beginning of a calendar year, regu-
20 lations under this section that impose new, signifi-
21 cant regulatory requirements on an eligible entity or
22 a Medicare Prescription Drug plan.

23 “(h) *RELATION TO STATE LAWS.*—

24 “(1) *IN GENERAL.*—The standards established
25 under this part shall supersede any State law or reg-

1 *ulation (including standards described in paragraph*
 2 *(2)) with respect to Medicare Prescription Drug plans*
 3 *which are offered by eligible entities under this*
 4 *part—*

5 *“(A) to the extent such law or regulation is*
 6 *inconsistent with such standards; and*

7 *“(B) in the same manner as such laws and*
 8 *regulations are superseded under section*
 9 *1856(b)(3).*

10 *“(2) STANDARDS SPECIFICALLY SUPERSEDED.—*
 11 *State standards relating to the following are super-*
 12 *seded under this section:*

13 *“(A) Benefit requirements, including re-*
 14 *quirements relating to cost-sharing and the*
 15 *structure of formularies.*

16 *“(B) Premiums.*

17 *“(C) Requirements relating to inclusion or*
 18 *treatment of providers.*

19 *“(D) Coverage determinations (including*
 20 *related appeals and grievance processes).*

21 *“(E) Requirements relating to marketing*
 22 *materials and summaries and schedules of bene-*
 23 *fits regarding a Medicare Prescription Drug*
 24 *plan.*

1 “(3) *PROHIBITION OF STATE IMPOSITION OF*
 2 *PREMIUM TAXES.*—*No State may impose a premium*
 3 *tax or similar tax with respect to—*

4 “(A) *monthly beneficiary obligations paid*
 5 *to the Administrator for Medicare Prescription*
 6 *Drug plans under this part; or*

7 “(B) *any payments made by the Adminis-*
 8 *trator under this part to an eligible entity offer-*
 9 *ing such a plan.*

10 *“Subpart 2—Prescription Drug Delivery System*

11 *“ESTABLISHMENT OF SERVICE AREAS*

12 *“SEC. 1860D–10. (a) ESTABLISHMENT.—*

13 “(1) *INITIAL ESTABLISHMENT.*—*Not later than*
 14 *April 15, 2005, the Administrator shall establish and*
 15 *publish the service areas in which Medicare Prescrip-*
 16 *tion Drug plans may offer benefits under this part.*

17 “(2) *PERIODIC REVIEW AND REVISION OF SERV-*
 18 *ICE AREAS.*—*The Administrator shall periodically re-*
 19 *view the service areas applicable under this section*
 20 *and, based on such review, may revise such service*
 21 *areas if the Administrator determines such revision to*
 22 *be appropriate.*

23 “(b) *REQUIREMENTS FOR ESTABLISHMENT OF SERV-*
 24 *ICE AREAS.—*

1 “(1) *IN GENERAL.*—*The Administrator shall es-*
2 *tablish the service areas under subsection (a) in a*
3 *manner that—*

4 “(A) *maximizes the availability of Medicare*
5 *Prescription Drug plans to eligible beneficiaries;*
6 *and*

7 “(B) *minimizes the ability of eligible enti-*
8 *ties offering such plans to favorably select eligible*
9 *beneficiaries.*

10 “(2) *ADDITIONAL REQUIREMENTS.*—*The Admin-*
11 *istrator shall establish the service areas under sub-*
12 *section (a) consistent with the following requirements:*

13 “(A) *There shall be at least 10 service areas.*

14 “(B) *Each service area must include at*
15 *least 1 State.*

16 “(C) *The Administrator may not divide*
17 *States so that portions of the State are in dif-*
18 *ferent service areas.*

19 “(D) *To the extent possible, the Adminis-*
20 *trator shall include multistate metropolitan sta-*
21 *tistical areas in a single service area. The Ad-*
22 *ministrator may divide metropolitan statistical*
23 *areas where it is necessary to establish service*
24 *areas of such size and geography as to maximize*

1 *the participation of Medicare Prescription Drug*
 2 *plans.*

3 “(3) *MAY CONFORM TO MEDICAREADVANTAGE*
 4 *PREFERRED PROVIDER REGIONS.—The Administrator*
 5 *may conform the service areas established under this*
 6 *section to the preferred provider regions established*
 7 *under section 1858(a)(3).*

8 “*PUBLICATION OF RISK ADJUSTERS*

9 “*SEC. 1860D–11. (a) PUBLICATION.—Not later than*
 10 *April 15 of each year (beginning in 2005), the Adminis-*
 11 *trator shall publish the risk adjusters established under sub-*
 12 *section (b) to be used in computing—*

13 “(1) *the amount of payment to Medicare Pre-*
 14 *scription Drug plans in the subsequent year under*
 15 *section 1860D–16(a), insofar as it is attributable to*
 16 *standard prescription drug coverage (or actuarially*
 17 *equivalent prescription drug coverage); and*

18 “(2) *the amount of payment to*
 19 *MedicareAdvantage plans in the subsequent year*
 20 *under section 1858A(c), insofar as it is attributable*
 21 *to standard prescription drug coverage (or actuarially*
 22 *equivalent prescription drug coverage).*

23 “(b) *ESTABLISHMENT OF RISK ADJUSTERS.—*

24 “(1) *IN GENERAL.—Subject to paragraph (2), the*
 25 *Administrator shall establish an appropriate method-*
 26 *ology for adjusting the amount of payment to plans*

1 referred to in subsection (a) to take into account vari-
 2 ation in costs based on the differences in actuarial
 3 risk of different enrollees being served. Any such risk
 4 adjustment shall be designed in a manner as to not
 5 result in a change in the aggregate payments de-
 6 scribed in paragraphs (1) and (2) of subsection (a).

7 “(2) *CONSIDERATIONS.*—In establishing the
 8 methodology under paragraph (1), the Administrator
 9 may take into account the similar methodologies used
 10 under section 1853(a)(3) to adjust payments to
 11 MedicareAdvantage organizations.

12 “(3) *DATA COLLECTION.*—In order to carry out
 13 this subsection, the Administrator shall require—

14 “(A) eligible entities to submit data regard-
 15 ing drug claims that can be linked at the bene-
 16 ficiary level to part A and part B data and such
 17 other information as the Administrator deter-
 18 mines necessary; and

19 “(B) MedicareAdvantage organizations (ex-
 20 cept MSA plans or a private fee-for-service plan
 21 that does not provide qualified prescription drug
 22 coverage) to submit data regarding drug claims
 23 that can be linked to other data that such orga-
 24 nizations are required to submit to the Adminis-

1 *trator and such other information as the Admin-*
 2 *istrator determines necessary.*

3 *“SUBMISSION OF BIDS FOR PROPOSED MEDICARE*
 4 *PRESCRIPTION DRUG PLANS*

5 *“SEC. 1860D–12. (a) SUBMISSION.—*

6 *“(1) IN GENERAL.—Each eligible entity that in-*
 7 *tends to offer a Medicare Prescription Drug plan in*
 8 *an area in a year (beginning with 2006) shall submit*
 9 *to the Administrator, at such time in the previous*
 10 *year and in such manner as the Administrator may*
 11 *specify, such information as the Administrator may*
 12 *require, including the information described in sub-*
 13 *section (b).*

14 *“(2) ANNUAL SUBMISSION.—An eligible entity*
 15 *shall submit the information required under para-*
 16 *graph (1) with respect to a Medicare Prescription*
 17 *Drug plan that the entity intends to offer on an an-*
 18 *nual basis.*

19 *“(b) INFORMATION DESCRIBED.—The information de-*
 20 *scribed in this subsection includes information on each of*
 21 *the following:*

22 *“(1) The benefits under the plan (as required*
 23 *under section 1860D–6).*

24 *“(2) The actuarial value of the qualified pre-*
 25 *scription drug coverage.*

1 “(3) *The amount of the monthly plan premium*
 2 *under the plan, including an actuarial certification*
 3 *of—*

4 “(A) *the actuarial basis for such monthly*
 5 *plan premium;*

6 “(B) *the portion of such monthly plan pre-*
 7 *mium attributable to standard prescription drug*
 8 *coverage or actuarially equivalent prescription*
 9 *drug coverage and, if applicable, to benefits that*
 10 *are in addition to such coverage; and*

11 “(C) *the reduction in such monthly plan*
 12 *premium resulting from the payments provided*
 13 *under section 1860D–20.*

14 “(4) *The service area for the plan.*

15 “(5) *Whether the entity plans to use any funds*
 16 *in the plan stabilization reserve fund in the Prescrip-*
 17 *tion Drug Account that are available to the entity to*
 18 *stabilize or reduce the monthly plan premium sub-*
 19 *mitted under paragraph (3), and if so, the amount in*
 20 *such reserve fund that is to be used.*

21 “(6) *Such other information as the Adminis-*
 22 *trator may require to carry out this part.*

23 “(c) *OPTIONS REGARDING SERVICE AREAS.—*

24 “(1) *IN GENERAL.—The service area of a Medi-*
 25 *care Prescription Drug plan shall be either—*

6 “(2) *RULE OF CONSTRUCTION.*—*Nothing in this*
7 *part shall be construed as prohibiting an eligible enti-*
8 *ty from submitting separate bids in multiple service*
9 *areas as long as each bid is for a single service area.*

12 “SEC. 1860D-13. (a) APPROVAL.—

17 “(2) *REQUIREMENTS FOR APPROVAL.*—The Ad-
18 ministrators may not approve a Medicare Prescription
19 Drug plan unless the following requirements are met:

23 “(B) APPLICATION OF FEHBP STANDARD.—

24 (i) The portion of the monthly plan premium

25 submitted under section 1860D–12(b) that is at-

26 tributable to standard prescription drug coverage

1 *reasonably and equitably reflects the actuarial*
 2 *value of the standard prescription drug coverage*
 3 *less the actuarial value of the reinsurance pay-*
 4 *ments under section 1860D–20 and the amount*
 5 *of any funds in the plan stabilization reserve*
 6 *fund in the Prescription Drug Account used to*
 7 *stabilize or reduce the monthly plan premium.*

8 “(ii) *If the plan provides additional pre-*
 9 *scription drug coverage pursuant to section*
 10 *1860D–6(a)(2), the monthly plan premium rea-*
 11 *sonably and equitably reflects the actuarial value*
 12 *of the coverage provided less the actuarial value*
 13 *of the reinsurance payments under section*
 14 *1860D–20 and the amount of any funds in the*
 15 *plan stabilization reserve fund in the Prescrip-*
 16 *tion Drug Account used to stabilize or reduce the*
 17 *monthly plan premium.*

18 “(b) *NEGOTIATION.—In exercising the authority under*
 19 *subsection (a), the Administrator shall have the authority*
 20 *to—*

21 “(1) *negotiate the terms and conditions of the*
 22 *proposed monthly plan premiums submitted and*
 23 *other terms and conditions of a proposed plan; and*

24 “(2) *disapprove, or limit enrollment in, a pro-*
 25 *posed plan based on—*

1 “(A) the costs to beneficiaries under the
2 plan;

3 “(B) the quality of the coverage and benefits
4 under the plan;

5 “(C) the adequacy of the network under the
6 plan;

7 “(D) the average aggregate projected cost of
8 covered drugs under the plan relative to other
9 Medicare Prescription Drug plans and
10 MedicareAdvantage plans; or

11 “(E) other factors determined appropriate
12 by the Administrator.

13 “(c) *SPECIAL RULES FOR APPROVAL.*—The Adminis-
14 trator may approve a Medicare Prescription Drug plan
15 submitted under section 1860D–12 only if the benefits
16 under such plan—

17 “(1) include the required benefits under section
18 1860D–6(a)(1); and

19 “(2) are not designed in such a manner that the
20 Administrator finds is likely to result in favorable se-
21 lection of eligible beneficiaries.

22 “(d) *ACCESS TO COMPETITIVE COVERAGE.*—

23 “(1) *NUMBER OF CONTRACTS.*—The Adminis-
24 trator, consistent with the requirements of this part
25 and the goal of containing costs under this title, shall,

1 *with respect to a year, approve at least 2 contracts*
 2 *to offer a Medicare Prescription Drug plan in each*
 3 *service area (established under section 1860D–10) for*
 4 *the year.*

5 “(2) *AUTHORITY TO REDUCE RISK TO ENSURE*
 6 *ACCESS.—*

7 “(A) *IN GENERAL.—Subject to subpara-*
 8 *graph (B), if the Administrator determines, with*
 9 *respect to an area, that the access required under*
 10 *paragraph (1) is not going to be provided in the*
 11 *area during the subsequent year, the Adminis-*
 12 *trator shall—*

13 “(i) *adjust the percents specified in*
 14 *paragraphs (2) and (4) of section 1860D–*
 15 *16(b) in an area in a year; or*

16 “(ii) *increase the percent specified in*
 17 *section 1860D–20(c)(1) in an area in a*
 18 *year.*

19 *The administrator shall exercise the authority*
 20 *under the preceding sentence only so long as*
 21 *(and to the extent) necessary to assure the access*
 22 *guaranteed under paragraph (1).*

23 “(B) *REQUIREMENTS FOR USE OF AUTHOR-*
 24 *ITY.—In exercising authority under subpara-*
 25 *graph (A), the Administrator—*

1 “(i) shall not provide for the full un-
 2 derwriting of financial risk for any eligible
 3 entity;

4 “(ii) shall not provide for any under-
 5 writing of financial risk for a public eligi-
 6 ble entity with respect to the offering of a
 7 nationwide Medicare Prescription Drug
 8 plan; and

9 “(iii) shall seek to maximize the as-
 10 sumption of financial risk by eligible enti-
 11 ties to ensure fair competition among Medi-
 12 care Prescription Drug plans.

13 “(C) REQUIREMENT TO ACCEPT 2 FULL-
 14 RISK QUALIFIED BIDS BEFORE EXERCISING AU-
 15 THORITY.—The Administrator may not exercise
 16 the authority under subparagraph (A) with re-
 17 spect to an area and year if 2 or more qualified
 18 bids are submitted by eligible entities to offer a
 19 Medicare Prescription Drug plan in the area for
 20 the year under paragraph (1) before the applica-
 21 tion of subparagraph (A).

22 “(D) REPORTS.—The Administrator, in
 23 each annual report to Congress under section
 24 1808(c)(1)(D), shall include information on the
 25 exercise of authority under subparagraph (A).

1 *The Administrator also shall include such rec-*
 2 *ommendations as may be appropriate to limit*
 3 *the exercise of such authority.*

4 “(e) *GUARANTEED ACCESS.*—

5 “(1) *ACCESS.*—*In order to assure access to quali-*
 6 *fied prescription drug coverage in an area, the Ad-*
 7 *ministrator shall take the following steps:*

8 “(A) *DETERMINATION.*—*Not later than Sep-*
 9 *tember 1 of each year (beginning in 2005) and*
 10 *for each area (established under section 1860D–*
 11 *10), the Administrator shall make a determina-*
 12 *tion as to whether the access required under sub-*
 13 *section (d)(1) is going to be provided in the area*
 14 *during the subsequent year. Such determination*
 15 *shall be made after the Administrator has exer-*
 16 *cised the authority under subsection (d)(2).*

17 “(B) *CONTRACT WITH AN ENTITY TO PRO-*
 18 *VIDE COVERAGE IN AN AREA.*—*Subject to para-*
 19 *graph (3), if the Administrator makes a deter-*
 20 *mination under subparagraph (A) that the ac-*
 21 *cess required under subsection (d)(1) is not going*
 22 *to be provided in an area during the subsequent*
 23 *year, the Administrator shall enter into a con-*
 24 *tract with an entity to provide eligible bene-*
 25 *ficiaries enrolled under this part (and not, ex-*

cept for an MSA plan or a private fee-for-service plan that does not provide qualified prescription drug coverage enrolled in a MedicareAdvantage plan) and residing in the area with standard prescription drug coverage (including access to negotiated prices for such beneficiaries pursuant to section 1860D–6(e)) during the subsequent year. An entity may be awarded a contract for more than 1 of the areas for which the Administrator is required to enter into a contract under this paragraph but the Administrator may enter into only 1 such contract in each such area.

“(C) *REQUIREMENT TO ACCEPT 2 REDUCED-RISK QUALIFIED BIDS BEFORE ENTERING INTO CONTRACT.*—The Administrator may not enter into a contract under subparagraph (B) with respect to an area and year if 2 or more qualified bids are submitted by eligible entities to offer a Medicare Prescription Drug plan in the area for the year after the Administrator has exercised the authority under subsection (d)(2) in the area for the year.

“(D) *ENTITY REQUIRED TO MEET BENEFICIARY PROTECTION AND OTHER REQUIREMENTS.*—An entity with a contract under sub-

paragraph (B) shall meet the requirements described in section 1860D–5 and such other requirements determined appropriate by the Administrator.

“(E) *COMPETITIVE PROCEDURES.*—Competitive procedures (as defined in section 4(5) of the Office of Federal Procurement Policy Act (41 U.S.C. 403(5))) shall be used to enter into a contract under subparagraph (B).

“(2) *MONTHLY BENEFICIARY OBLIGATION FOR ENROLLMENT.*—

“(A) *IN GENERAL.*—In the case of an eligible beneficiary receiving access to qualified prescription drug coverage through enrollment with an entity with a contract under paragraph (1)(B), the monthly beneficiary obligation of such beneficiary for such enrollment shall be an amount equal to the applicable percent (as determined under section 1860D–17(c)) of the monthly national average premium (as computed under section 1860D–15) for the area for the year, as adjusted using the geographic adjuster under subparagraph (B).

“(B) *ESTABLISHMENT OF GEOGRAPHIC ADJUSTER.*—The Administrator shall establish an

appropriate methodology for adjusting the monthly beneficiary obligation (as computed under subparagraph (A)) for the year in an area to take into account differences in drug prices among areas. In establishing such methodology, the Administrator may take into account differences in drug utilization between eligible beneficiaries in an area and eligible beneficiaries in other areas and the results of the ongoing study required under section 106 of the Prescription Drug and Medicare Improvement Act of 2003. Any such adjustment shall be applied in a manner so as to not result in a change in the aggregate payments made under this part that would have been made if the Administrator had not applied such adjustment.

“(3) PAYMENTS UNDER THE CONTRACT.—

“(A) IN GENERAL.—A contract entered into under paragraph (1)(B) shall provide for—

“(i) payment for the negotiated costs of covered drugs provided to eligible beneficiaries enrolled with the entity; and

“(ii) payment of prescription management fees that are tied to performance requirements established by the Administrator

1 *for the management, administration, and*
 2 *delivery of the benefits under the contract.*

3 “(B) *PERFORMANCE REQUIREMENTS.—The*
 4 *performance requirements established by the Ad-*
 5 *ministrator pursuant to subparagraph (A)(ii)*
 6 *shall include the following:*

7 “(i) *The entity contains costs to the*
 8 *Prescription Drug Account and to eligible*
 9 *beneficiaries enrolled under this part and*
 10 *with the entity.*

11 “(ii) *The entity provides such bene-*
 12 *ficiaries with quality clinical care.*

13 “(iii) *The entity provides such bene-*
 14 *ficiaries with quality services.*

15 “(C) *ENTITY ONLY AT RISK TO THE EXTENT*
 16 *OF THE FEES TIED TO PERFORMANCE REQUIRE-*
 17 *MENTS.—An entity with a contract under para-*
 18 *graph (1)(B) shall only be at risk for the provi-*
 19 *sion of benefits under the contract to the extent*
 20 *that the management fees paid to the entity are*
 21 *tied to performance requirements under subpara-*
 22 *graph (A)(ii).*

23 “(4) *ELIGIBLE ENTITY THAT SUBMITTED A BID*
 24 *FOR THE AREA NOT ELIGIBLE TO BE AWARDED THE*
 25 *CONTRACT.—An eligible entity that submitted a bid to*

1 *offer a Medicare Prescription Drug plan for an area*
 2 *for a year under section 1860D–12, including a bid*
 3 *submitted after the Administrator has exercised the*
 4 *authority under subsection (d)(2), may not be award-*
 5 *ed a contract under paragraph (1)(B) for that area*
 6 *and year. The previous sentence shall apply to an en-*
 7 *tity that was awarded a contract under paragraph*
 8 *(1)(B) for the area in the previous year and sub-*
 9 *mitted such a bid under section 1860D–12 for the*
 10 *year.*

11 *“(5) TERM OF CONTRACT.—A contract entered*
 12 *into under paragraph (1)(B) shall be for a 1-year pe-*
 13 *riod. Such contract may provide for renewal at the*
 14 *discretion of the Administrator if the Administrator*
 15 *is required to enter into a contract under such para-*
 16 *graph with respect to the area covered by such con-*
 17 *tract for the subsequent year.*

18 *“(6) ENTITY NOT PERMITTED TO MARKET OR*
 19 *BRAND THE CONTRACT.—An entity with a contract*
 20 *under paragraph (1)(B) may not engage in any mar-*
 21 *keting or branding of such contract.*

22 *“(7) RULES FOR AREAS WHERE ONLY 1 COM-*
 23 *PETITIVELY BID PLAN WAS APPROVED.—In the case of*
 24 *an area where (before the application of this sub-*

1 *section) only 1 Medicare Prescription Drug plan was*
 2 *approved for a year—*

3 *“(A) the plan may (at the option of the*
 4 *plan) be offered in the area for the year (under*
 5 *rules applicable to such plans under this part*
 6 *and not under this subsection);*

7 *“(B) eligible beneficiaries described in para-*
 8 *graph (1)(B) may receive access to qualified pre-*
 9 *scription drug coverage through enrollment in*
 10 *the plan or with an entity with a contract under*
 11 *paragraph (1)(B); and*

12 *“(C) for purposes of applying section*
 13 *1860D–3(a)(1)(A)(ii), such plan shall be the*
 14 *plan designated in the area under such section.*

15 *“(f) TWO-YEAR CONTRACTS.—Except for a contract*
 16 *entered into under subsection (e)(1)(B), a contract approved*
 17 *under this part shall be for a 2-year period.*

18 *“COMPUTATION OF MONTHLY STANDARD PRESCRIPTION*
 19 *DRUG COVERAGE PREMIUMS*

20 *“SEC. 1860D–14. (a) IN GENERAL.—For each year*
 21 *(beginning with 2006), the Administrator shall compute a*
 22 *monthly standard prescription drug coverage premium for*
 23 *each Medicare Prescription Drug plan approved under sec-*
 24 *tion 1860D–13 and for each MedicareAdvantage plan.*

1 “(b) *REQUIREMENTS.*—*The monthly standard pre-*
 2 *scription drug coverage premium for a plan for a year shall*
 3 *be equal to—*

4 “(1) *in the case of a plan offered by an eligible*
 5 *entity or MedicareAdvantage organization that pro-*
 6 *vides standard prescription drug coverage or an actu-*
 7 *arially equivalent prescription drug coverage and*
 8 *does not provide additional prescription drug cov-*
 9 *erage pursuant to section 1860D–6(a)(2), the monthly*
 10 *plan premium approved for the plan under section*
 11 *1860D–13 for the year; and*

12 “(2) *in the case of a plan offered by an eligible*
 13 *entity or MedicareAdvantage organization that pro-*
 14 *vides additional prescription drug coverage pursuant*
 15 *to section 1860D–6(a)(2)—*

16 “(A) *an amount that reflects only the actu-*
 17 *arial value of the standard prescription drug*
 18 *coverage offered under the plan; or*

19 “(B) *if determined appropriate by the Ad-*
 20 *ministrator, the monthly plan premium ap-*
 21 *proved under section 1860D–13 for the year for*
 22 *the Medicare Prescription Drug plan (or, if ap-*
 23 *plicable, the MedicareAdvantage plan) that, as*
 24 *required under section 1860D–6(a)(2)(B) for a*

1 *Medicare Prescription Drug plans and a*
 2 *MedicareAdvantage plan—*

3 “(i) *is offered by such entity or organi-*
 4 *zation in the same area as the plan; and*

5 “(ii) *does not provide additional pre-*
 6 *scription drug coverage pursuant to such*
 7 *section.*

8 “*COMPUTATION OF MONTHLY NATIONAL AVERAGE PREMIUM*

9 “*SEC. 1860D–15. (a) COMPUTATION.—*

10 “(1) *IN GENERAL.—For each year (beginning*
 11 *with 2006) the Administrator shall compute a month-*
 12 *ly national average premium equal to the average of*
 13 *the monthly standard prescription drug coverage pre-*
 14 *mium for each Medicare Prescription Drug plan and*
 15 *each MedicareAdvantage plan (as computed under*
 16 *section 1860D–14). Such premium may be adjusted*
 17 *pursuant to any methodology determined under sub-*
 18 *section (b), as determined appropriate by the Admin-*
 19 *istrator.*

20 “(2) *WEIGHTED AVERAGE.—The monthly na-*
 21 *tional average premium computed under paragraph*
 22 *(1) shall be a weighted average, with the weight for*
 23 *each plan being equal to the average number of bene-*
 24 *ficiaries enrolled under such plan in the previous*
 25 *year.*

1 “(b) *GEOGRAPHIC ADJUSTMENT.*—*The Administrator*
2 *shall establish an appropriate methodology for adjusting the*
3 *monthly national average premium (as computed under*
4 *subsection (a)) for the year in an area to take into account*
5 *differences in prices for covered drugs among different*
6 *areas. In establishing such methodology, the Administrator*
7 *may take into account differences in drug utilization be-*
8 *tween eligible beneficiaries in that area and other eligible*
9 *beneficiaries and the results of the ongoing study required*
10 *under section 106 of the Prescription Drug and Medicare*
11 *Improvement Act of 2003. Any such adjustment shall be ap-*
12 *plied in a manner as to not result in a change in aggregate*
13 *payments made under this part than would have been made*
14 *if the Administrator had not applied such adjustment.*

15 “(c) *SPECIAL RULE FOR 2006.*—*For purposes of ap-*
16 *plying this section for 2006, the Administrator shall estab-*
17 *lish procedures for determining the weighted average under*
18 *subsection (a)(2) for 2005.*

19 “*PAYMENTS TO ELIGIBLE ENTITIES*

20 “*SEC. 1860D–16. (a) PAYMENT OF MONTHLY PLAN*
21 *PREMIUMS.*—*For each year (beginning with 2006), the Ad-*
22 *ministrator shall pay to each entity offering a Medicare*
23 *Prescription Drug plan in which an eligible beneficiary is*
24 *enrolled an amount equal to the full amount of the monthly*
25 *plan premium approved for the plan under section 1860D–*
26 *13 on behalf of each eligible beneficiary enrolled in such*

1 *plan for the year, as adjusted using the risk adjusters that*
 2 *apply to the standard prescription drug coverage published*
 3 *under section 1860D–11.*

4 “(b) *PORTION OF TOTAL PAYMENTS OF MONTHLY*
 5 *PLAN PREMIUMS SUBJECT TO RISK.—*

6 “(1) *NOTIFICATION OF SPENDING UNDER THE*
 7 *PLAN.—*

8 “(A) *IN GENERAL.—For each year (begin-*
 9 *ning in 2007), the eligible entity offering a*
 10 *Medicare Prescription Drug plan shall notify the*
 11 *Administrator of the following:*

12 “(i) *TOTAL ACTUAL COSTS.—The total*
 13 *amount of costs that the entity incurred in*
 14 *providing standard prescription drug cov-*
 15 *erage (or prescription drug coverage that is*
 16 *actuarially equivalent pursuant to section*
 17 *1860D–6(a)(1)(B)) for all enrollees under*
 18 *the plan in the previous year.*

19 “(ii) *AMOUNTS RESULTING IN ACTUAL*
 20 *COSTS.—With respect to the total amount*
 21 *under clause (i) for the year—*

22 “(I) *the aggregate amount of pay-*
 23 *ments made by the entity to phar-*
 24 *macies and other entities with respect*
 25 *to such coverage for such enrollees; and*

1 “(II) the aggregate amount of dis-
 2 counts, direct or indirect subsidies, re-
 3 bates, or other price concessions or di-
 4 rect or indirect remunerations made to
 5 the entity with respect to such coverage
 6 for such enrollees.

7 “(B) CERTAIN EXPENSES NOT INCLUDED.—
 8 The amount under subparagraph (A)(i) may not
 9 include—

10 “(i) administrative expenses incurred
 11 in providing the coverage described in sub-
 12 paragraph (A)(i);

13 “(ii) amounts expended on providing
 14 additional prescription drug coverage pur-
 15 suant to section 1860D–6(a)(2);

16 “(iii) amounts expended for which the
 17 entity is subsequently provided with rein-
 18 surance payments under section 1860D–20;
 19 or

20 “(iv) discounts, direct or indirect sub-
 21 sidies, rebates, or other price concessions or
 22 direct or indirect remunerations made to
 23 the entity with respect to coverage described
 24 in subparagraph (A)(i).

25 “(2) ADJUSTMENT OF PAYMENT.—

1 “(A) *NO ADJUSTMENT IF ALLOWABLE COSTS*
 2 *WITHIN RISK CORRIDOR.*—*If the allowable costs*
 3 *(specified in paragraph (3)) for the plan for the*
 4 *year are not more than the first threshold upper*
 5 *limit of the risk corridor (specified in paragraph*
 6 *(4)(A)(iii)) and are not less than the first thresh-*
 7 *old lower limit of the risk corridor (specified in*
 8 *paragraph (4)(A)(i)) for the plan for the year,*
 9 *then no additional payments shall be made by*
 10 *the Administrator and no payments shall be*
 11 *made by (or collected from) the eligible entity of-*
 12 *fering the plan.*

13 “(B) *INCREASE IN PAYMENT IF ALLOWABLE*
 14 *COSTS ABOVE UPPER LIMIT OF RISK COR-*
 15 *RIDOR.*—

16 “(i) *IN GENERAL.*—*If the allowable*
 17 *costs for the plan for the year are more than*
 18 *the first threshold upper limit of the risk*
 19 *corridor for the plan for the year, then the*
 20 *Administrator shall increase the total of the*
 21 *monthly payments made to the entity offer-*
 22 *ing the plan for the year under subsection*
 23 *(a) by an amount equal to the sum of—*

24 “(I) *the applicable percent (as de-*
 25 *finied in subparagraph (D)) of such al-*

1 lowable costs which are more than such
 2 first threshold upper limit of the risk
 3 corridor and not more than the second
 4 threshold upper limit of the risk cor-
 5 ridor for the plan for the year (as spec-
 6 ified under paragraph (4)(A)(iv)); and
 7 “(II) 90 percent of such allowable
 8 costs which are more than such second
 9 threshold upper limit of the risk cor-
 10 ridor.
 11 “(ii) *SPECIAL TRANSITIONAL COR-*
 12 *RIDOR FOR 2006 AND 2007.*—If the Adminis-
 13 trator determines with respect to 2006 or
 14 2007 that at least 60 percent of Medicare
 15 Prescription Drug plans and
 16 MedicareAdvantage Plans (excluding MSA
 17 plans or private fee-for-service plans that do
 18 not provide qualified prescription drug cov-
 19 erage) have allowable costs for the plan for
 20 the year that are more than the first thresh-
 21 old upper limit of the risk corridor for the
 22 plan for the year and that such plans rep-
 23 resent at least 60 percent of eligible bene-
 24 ficiaries enrolled under this part, clause

1 *(i)(I) shall be applied by substituting ‘90*
 2 *percent’ for ‘applicable percent’.*

3 *“(C) PLAN PAYMENT IF ALLOWABLE COSTS*
 4 *BELOW LOWER LIMIT OF RISK CORRIDOR.—If the*
 5 *allowable costs for the plan for the year are less*
 6 *than the first threshold lower limit of the risk*
 7 *corridor for the plan for the year, then the entity*
 8 *offering the plan shall a make a payment to the*
 9 *Administrator of an amount (or the Adminis-*
 10 *trator shall otherwise recover from the plan an*
 11 *amount) equal to—*

12 *“(i) the applicable percent (as so de-*
 13 *finied) of such allowable costs which are less*
 14 *than such first threshold lower limit of the*
 15 *risk corridor and not less than the second*
 16 *threshold lower limit of the risk corridor for*
 17 *the plan for the year (as specified under*
 18 *paragraph (4)(A)(ii)); and*

19 *“(ii) 90 percent of such allowable costs*
 20 *which are less than such second threshold*
 21 *lower limit of the risk corridor.*

22 *“(D) APPLICABLE PERCENT DEFINED.—For*
 23 *purposes of this paragraph, the term ‘applicable*
 24 *percent’ means—*

1 “(i) for 2006 and 2007, 75 percent;

2 and

3 “(ii) for 2008 and subsequent years, 50

4 percent.

5 “(3) *ESTABLISHMENT OF ALLOWABLE COSTS.—*

6 *For each year, the Administrator shall establish the*
 7 *allowable costs for each Medicare Prescription Drug*
 8 *plan for the year. The allowable costs for a plan for*
 9 *a year shall be equal to the amount described in*
 10 *paragraph (1)(A)(i) for the plan for the year.*

11 “(4) *ESTABLISHMENT OF RISK CORRIDORS.—*

12 “(A) *IN GENERAL.—For each year (begin-*
 13 *ning with 2006), the Administrator shall estab-*
 14 *lish a risk corridor for each Medicare Prescrip-*
 15 *tion Drug plan. The risk corridor for a plan for*
 16 *a year shall be equal to a range as follows:*

17 “(i) *FIRST THRESHOLD LOWER*
 18 *LIMIT.—The first threshold lower limit of*
 19 *such corridor shall be equal to—*

20 “(I) *the target amount described*
 21 *in subparagraph (B) for the plan;*
 22 *minus*

23 “(II) *an amount equal to the first*
 24 *threshold risk percentage for the plan*

1 (as determined under subparagraph
2 (C)(i)) of such target amount.

3 “(ii) *SECOND THRESHOLD LOWER*
4 *LIMIT.—The second threshold lower limit of*
5 *such corridor shall be equal to—*

6 “(I) *the target amount described*
7 *in subparagraph (B) for the plan;*
8 *minus*

9 “(II) *an amount equal to the sec-*
10 *ond threshold risk percentage for the*
11 *plan (as determined under subpara-*
12 *graph (C)(i)) of such target amount.*

13 “(iii) *FIRST THRESHOLD UPPER*
14 *LIMIT.—The first threshold upper limit of*
15 *such corridor shall be equal to the sum of—*

16 “(I) *such target amount; and*

17 “(II) *the amount described in*
18 *clause (i)(II).*

19 “(iv) *SECOND THRESHOLD UPPER*
20 *LIMIT.—The second threshold upper limit of*
21 *such corridor shall be equal to the sum of—*

22 “(I) *such target amount; and*

23 “(II) *the amount described in*
24 *clause (ii)(II).*

1 “(B) *TARGET AMOUNT DESCRIBED.*—The
2 *target amount described in this paragraph is,*
3 *with respect to a Medicare Prescription Drug*
4 *plan offered by an eligible entity in a year—*

5 “(i) *in the case of a plan offered by an*
6 *eligible entity that provides standard pre-*
7 *scription drug coverage or actuarially*
8 *equivalent prescription drug coverage and*
9 *does not provide additional prescription*
10 *drug coverage pursuant to section 1860D–*
11 *6(a)(2), an amount equal to the total of the*
12 *monthly plan premiums paid to such entity*
13 *for such plan for the year pursuant to sub-*
14 *section (a), reduced by the percentage speci-*
15 *fied in subparagraph (D); and*

16 “(ii) *in the case of a plan offered by*
17 *an eligible entity that provides additional*
18 *prescription drug coverage pursuant to sec-*
19 *tion 1860D–6(a)(2), an amount equal to the*
20 *total of the monthly plan premiums paid to*
21 *such entity for such plan for the year pur-*
22 *suant to subsection (a) that are related to*
23 *standard prescription drug coverage (deter-*
24 *mined using the rules under section 1860D–*

1 14(b)), reduced by the percentage specified
2 in subparagraph (D).

3 “(C) *FIRST AND SECOND THRESHOLD RISK*
4 *PERCENTAGE DEFINED.*—

5 “(i) *FIRST THRESHOLD RISK PER-*
6 *CENTAGE.*—Subject to clause (iii), for pur-
7 poses of this section, the first threshold risk
8 percentage is—

9 “(I) for 2006 and 2007, and 2.5
10 percent;

11 “(II) for 2008 through 2011, 5
12 percent; and

13 “(III) for 2012 and subsequent
14 years, a percentage established by the
15 Administrator, but in no case less than
16 5 percent.

17 “(ii) *SECOND THRESHOLD RISK PER-*
18 *CENTAGE.*—Subject to clause (iii), for pur-
19 poses of this section, the second threshold
20 risk percentage is—

21 “(I) for 2006 and 2007, 5.0 per-
22 cent;

23 “(II) for 2008 through 2011, 10
24 percent

1 “(III) for 2012 and subsequent
 2 years, a percentage established by the
 3 Administrator that is greater than the
 4 percent established for the year under
 5 clause (i)(III), but in no case less than
 6 10 percent.

7 “(iii) *REDUCTION OF RISK PERCENT-*
 8 *AGE TO ENSURE 2 PLANS IN AN AREA.—*
 9 *Pursuant to paragraph (2) of section*
 10 *1860D–13(d), the Administrator may re-*
 11 *duce the applicable first or second threshold*
 12 *risk percentage in an area in a year in*
 13 *order to ensure the access to plans required*
 14 *under paragraph (1) of such section.*

15 “(D) *TARGET AMOUNT NOT TO INCLUDE AD-*
 16 *MINISTRATIVE EXPENSES NEGOTIATED BETWEEN*
 17 *THE ADMINISTRATOR AND THE ENTITY OFFERING*
 18 *THE PLAN.—For each year (beginning in 2006),*
 19 *the Administrator and the entity offering a*
 20 *Medicare Prescription Drug plan shall negotiate,*
 21 *as part of the negotiation process described in*
 22 *section 1860D–13(b) during the previous year,*
 23 *the percentage of the payments to the entity*
 24 *under subsection (a) with respect to the plan*
 25 *that are attributable and reasonably incurred for*

1 *administrative expenses for providing standard*
 2 *prescription drug coverage or actuarially equiva-*
 3 *lent prescription drug coverage in the year.*

4 “(5) *PLANS AT RISK FOR ENTIRE AMOUNT OF*
 5 *ADDITIONAL PRESCRIPTION DRUG COVERAGE.—An el-*
 6 *igible entity that offers a Medicare Prescription Drug*
 7 *plan that provides additional prescription drug cov-*
 8 *erage pursuant to section 1860D–6(a)(2) shall be at*
 9 *full financial risk for the provision of such additional*
 10 *coverage.*

11 “(6) *NO EFFECT ON ELIGIBLE BENEFICIARIES.—*
 12 *No change in payments made by reason of this sub-*
 13 *section shall affect the beneficiary obligation under*
 14 *section 1860D–17 for the year in which such change*
 15 *in payments is made.*

16 “(7) *DISCLOSURE OF INFORMATION.—*

17 “(A) *IN GENERAL.—Each contract under*
 18 *this part shall provide that—*

19 “(i) *the entity offering a Medicare Pre-*
 20 *scription Drug plan shall provide the Ad-*
 21 *ministrator with such information as the*
 22 *Administrator determines is necessary to*
 23 *carry out this section; and*

24 “(ii) *the Administrator shall have the*
 25 *right to inspect and audit any books and*

1 *records of the eligible entity that pertain to*
 2 *the information regarding costs provided to*
 3 *the Administrator under paragraph (1).*

4 “(B) *RESTRICTION ON USE OF INFORMA-*
 5 *TION.—Information disclosed or obtained pursu-*
 6 *ant to the provisions of this section may be used*
 7 *by officers and employees of the Department of*
 8 *Health and Human Services only for the pur-*
 9 *poses of, and to the extent necessary in, carrying*
 10 *out this section.*

11 “(c) *STABILIZATION RESERVE FUND.—*

12 “(1) *ESTABLISHMENT.—*

13 “(A) *IN GENERAL.—There is established,*
 14 *within the Prescription Drug Account, a sta-*
 15 *bilization reserve fund in which the Adminis-*
 16 *trator shall deposit amounts on behalf of eligible*
 17 *entities in accordance with paragraph (2) and*
 18 *such amounts shall be made available by the Sec-*
 19 *retary for the use of eligible entities in contract*
 20 *year 2008 and subsequent contract years in ac-*
 21 *cordance with paragraph (3).*

22 “(B) *REVERSION OF UNUSED AMOUNTS.—*
 23 *Any amount in the stabilization reserve fund es-*
 24 *tablished under subparagraph (A) that is not ex-*
 25 *pende*
 ded by an eligible entity in accordance with

1 *paragraph (3) or that was deposited for the use*
 2 *of an eligible entity that no longer has a contract*
 3 *under this part shall revert for the use of the*
 4 *Prescription Drug Account.*

5 “(2) *DEPOSIT OF AMOUNTS FOR 5 YEARS.*—

6 “(A) *IN GENERAL.*—*If the target amount for*
 7 *a Medicare Prescription Drug plan for 2006,*
 8 *2007, 2008, 2009, or 2010 (as determined under*
 9 *subsection (b)(4)(B)) exceeds the applicable costs*
 10 *for the plan for the year by more than 3 percent,*
 11 *then—*

12 “(i) *the entity offering the plan shall*
 13 *make a payment to the Administrator of an*
 14 *amount (or the Administrator shall other-*
 15 *wise recover from the plan an amount)*
 16 *equal to the portion of such excess that is in*
 17 *excess of 3 percent of the target amount;*
 18 *and*

19 “(ii) *the Administrator shall deposit*
 20 *an amount equal to the amount collected or*
 21 *otherwise recovered under clause (i) in the*
 22 *stabilization reserve fund on behalf of the el-*
 23 *igible entity offering such plan.*

24 “(B) *APPLICABLE COSTS.*—*For purposes of*
 25 *subparagraph (A), the term ‘applicable costs’*

means, with respect to a Medicare Prescription Drug plan and year, an amount equal the sum of—

“(i) the allowable costs for the plan and year (as determined under subsection (b)(3)(A); and

“(ii) the total amount by which monthly payments to the plan were reduced (or otherwise recovered from the plan) for the year under subsection (b)(2)(C).

“(3) *USE OF RESERVE FUND TO STABILIZE OR REDUCE MONTHLY PLAN PREMIUMS.*—

“(A) *IN GENERAL.*—For any contract year beginning after 2007, an eligible entity offering a Medicare Prescription Drug plan may use funds in the stabilization reserve fund in the Prescription Drug Account that were deposited in such fund on behalf of the entity to stabilize or reduce monthly plan premiums submitted under section 1860D–12(b)(3).

“(B) *PROCEDURES.*—The Administrator shall establish procedures for—

“(i) reducing monthly plan premiums submitted under section 1860D–12(b)(3) pursuant to subparagraph (A); and

1 “(ii) making payments from the plan
 2 stabilization reserve fund in the Prescrip-
 3 tion Drug Account to eligible entities that
 4 inform the Secretary under section 1860D–
 5 12(b)(5) of the entity’s intent to use funds
 6 in such reserve fund to reduce such pre-
 7 miums.

8 “(d) PORTION OF PAYMENTS OF MONTHLY PLAN PRE-
 9 MIUMS ATTRIBUTABLE TO ADMINISTRATIVE EXPENSES
 10 TIED TO PERFORMANCE REQUIREMENTS.—

11 “(1) IN GENERAL.—The Administrator shall es-
 12 tablish procedures to adjust the portion of the pay-
 13 ments made to an entity under subsection (a) that are
 14 attributable to administrative expenses (as deter-
 15 mined pursuant to subsection (b)(4)(D)) to ensure
 16 that the entity meets the performance requirements
 17 described in clauses (ii) and (iii) of section 1860D–
 18 13(e)(4)(B).

19 “(2) NO EFFECT ON ELIGIBLE BENEFICIARIES.—
 20 No change in payments made by reason of this sub-
 21 section shall affect the beneficiary obligation under
 22 section 1860D–17 for the year in which such change
 23 in payments is made.

24 “(e) PAYMENT TERMS.—

1 “(1) *ADMINISTRATOR PAYMENTS.*—*Payments to*
 2 *an entity offering a Medicare Prescription Drug plan*
 3 *under this section shall be made in a manner deter-*
 4 *mined by the Administrator and based upon the man-*
 5 *ner in which payments are made under section*
 6 *1853(a) (relating to payments to MedicareAdvantage*
 7 *organizations).*

8 “(2) *PLAN PAYMENTS.*—*The Administrator shall*
 9 *establish a process for collecting (or other otherwise*
 10 *recovering) amounts that an entity offering a Medi-*
 11 *care Prescription Drug plan is required to make to*
 12 *the Administrator under this section.*

13 “(f) *PAYMENTS TO MEDICAREADVANTAGE PLANS.*—
 14 *For provisions related to payments to MedicareAdvantage*
 15 *organizations offering MedicareAdvantage plans for quali-*
 16 *fied prescription drug coverage made available under the*
 17 *plan, see section 1858A(c).*

18 “(g) *SECONDARY PAYER PROVISIONS.*—*The provisions*
 19 *of section 1862(b) shall apply to the benefits provided under*
 20 *this part.*

21 “*COMPUTATION OF MONTHLY BENEFICIARY OBLIGATION*

22 “*SEC. 1860D–17. (a) BENEFICIARIES ENROLLED IN A*
 23 *MEDICARE PRESCRIPTION DRUG PLAN.*—*In the case of an*
 24 *eligible beneficiary enrolled under this part and in a Medi-*
 25 *care Prescription Drug plan, the monthly beneficiary obli-*

1 gation for enrollment in such plan in a year shall be deter-
 2 mined as follows:

3 “(1) *MONTHLY PLAN PREMIUM EQUALS MONTHLY*
 4 *NATIONAL AVERAGE PREMIUM.*—If the amount of the
 5 monthly plan premium approved by the Adminis-
 6 trator under section 1860D–13 for a Medicare Pre-
 7 scription Drug plan for the year is equal to the
 8 monthly national average premium (as computed
 9 under section 1860D–15) for the area for the year, the
 10 monthly beneficiary obligation of the eligible bene-
 11 ficiary in that year shall be an amount equal to the
 12 applicable percent (as determined in subsection (c)) of
 13 the amount of such monthly national average pre-
 14 mium.

15 “(2) *MONTHLY PLAN PREMIUM LESS THAN*
 16 *MONTHLY NATIONAL AVERAGE PREMIUM.*—If the
 17 amount of the monthly plan premium approved by
 18 the Administrator under section 1860D–13 for the
 19 Medicare Prescription Drug plan for the year is less
 20 than the monthly national average premium (as com-
 21 puted under section 1860D–15) for the area for the
 22 year, the monthly beneficiary obligation of the eligible
 23 beneficiary in that year shall be an amount equal
 24 to—

1 “(A) the applicable percent of the amount of
2 such monthly national average premium; minus

3 “(B) the amount by which such monthly
4 national average premium exceeds the amount of
5 the monthly plan premium approved by the Ad-
6 ministrators for the plan.

7 “(3) MONTHLY PLAN PREMIUM EXCEEDS MONTH-
8 LY NATIONAL AVERAGE PREMIUM.—If the amount of
9 the monthly plan premium approved by the Adminis-
10 trator under section 1860D–13 for a Medicare Pre-
11 scription Drug plan for the year exceeds the monthly
12 national average premium (as computed under sec-
13 tion 1860D–15) for the area for the year, the monthly
14 beneficiary obligation of the eligible beneficiary in
15 that year shall be an amount equal to the sum of—

16 “(A) the applicable percent of the amount of
17 such monthly national average premium; plus

18 “(B) the amount by which the monthly plan
19 premium approved by the Administrator for the
20 plan exceeds the amount of such monthly na-
21 tional average premium.

22 “(b) BENEFICIARIES ENROLLED IN A
23 MEDICAREADVANTAGE PLAN.—In the case of an eligible
24 beneficiary that is enrolled in a MedicareAdvantage plan
25 (except for an MSA plan or a private fee-for-service plan

1 *that does not provide qualified prescription drug coverage),*
 2 *the Medicare monthly beneficiary obligation for qualified*
 3 *prescription drug coverage shall be determined pursuant to*
 4 *section 1858A(d).*

5 “(c) *APPLICABLE PERCENT.*—*For purposes of this sec-*
 6 *tion, except as provided in section 1860D–19 (relating to*
 7 *premium subsidies for low-income individuals), the appli-*
 8 *cable percent for any year is the percentage equal to a*
 9 *fraction—*

10 “(1) *the numerator of which is 30 percent; and*

11 “(2) *the denominator of which is 100 percent*
 12 *minus a percentage equal to—*

13 “(A) *the total reinsurance payments which*
 14 *the Administrator estimates will be made under*
 15 *section 1860D–20 to qualifying entities described*
 16 *in subsection (e)(3) of such section during the*
 17 *year; divided by*

18 “(B) *the sum of—*

19 “(i) *the amount estimated under sub-*
 20 *paragraph (A) for the year; and*

21 “(ii) *the total payments which the Ad-*
 22 *ministrator estimates will be made under*
 23 *sections 1860D–16 and 1858A(c) during the*
 24 *year that relate to standard prescription*

1 *drug coverage (or actuarially equivalent*
 2 *prescription drug coverage).*

3 “COLLECTION OF MONTHLY BENEFICIARY OBLIGATION

4 “SEC. 1860D–18. (a) COLLECTION OF AMOUNT IN
 5 SAME MANNER AS PART B PREMIUM.—

6 “(1) *IN GENERAL.*—Subject to paragraph (2), the
 7 *amount of the monthly beneficiary obligation (deter-*
 8 *mined under section 1860D–17) applicable to an eli-*
 9 *gible beneficiary under this part (after application of*
 10 *any increase under section 1860D–2(b)(1)(A)) shall*
 11 *be collected and credited to the Prescription Drug Ac-*
 12 *count in the same manner as the monthly premium*
 13 *determined under section 1839 is collected and cred-*
 14 *ited to the Federal Supplementary Medical Insurance*
 15 *Trust Fund under section 1840.*

16 “(2) *PROCEDURES FOR SPONSOR TO PAY OBLIGA-*
 17 *TION ON BEHALF OF RETIREE.*—The Administrator
 18 *shall establish procedures under which an eligible ben-*
 19 *eficiary enrolled in a Medicare Prescription Drug*
 20 *plan may elect to have the sponsor (as defined in*
 21 *paragraph (5) of section 1860D–20(e)) of employ-*
 22 *ment-based retiree health coverage (as defined in*
 23 *paragraph (4)(B) of such section) in which the bene-*
 24 *ficiary is enrolled pay the amount of the monthly*
 25 *beneficiary obligation applicable to the beneficiary*
 26 *under this part directly to the Administrator.*

1 “(b) *INFORMATION NECESSARY FOR COLLECTION.*—In
 2 order to carry out subsection (a), the Administrator shall
 3 transmit to the Commissioner of Social Security—

4 “(1) by the beginning of each year, the name, so-
 5 cial security account number, monthly beneficiary ob-
 6 ligation owed by each individual enrolled in a Medi-
 7 care Prescription Drug plan for each month during
 8 the year, and other information determined appro-
 9 priate by the Administrator; and

10 “(2) periodically throughout the year, informa-
 11 tion to update the information previously transmitted
 12 under this paragraph for the year.

13 “(c) *COLLECTION FOR BENEFICIARIES ENROLLED IN*
 14 *A MEDICAREADVANTAGE PLAN.*—For provisions related to
 15 the collection of the monthly beneficiary obligation for
 16 qualified prescription drug coverage under a
 17 MedicareAdvantage plan, see section 1858A(e).

18 “*PREMIUM AND COST-SHARING SUBSIDIES FOR LOW-*
 19 *INCOME INDIVIDUALS*

20 “*SEC. 1860D–19. (a) AMOUNT OF SUBSIDIES.*—

21 “(1) *FULL PREMIUM SUBSIDY AND REDUCTION*
 22 *OF COST-SHARING FOR QUALIFIED MEDICARE BENE-*
 23 *FICIARIES.*—In the case of a qualified medicare bene-
 24 ficiary (as defined in paragraph (4)(A))—

25 “(A) section 1860D–17 shall be applied—

1 “(i) in subsection (c), by substituting
 2 ‘0 percent’ for the applicable percent that
 3 would otherwise apply under such sub-
 4 section; and

5 “(ii) in subsection (a)(3)(B), by sub-
 6 stituting ‘the amount of the monthly plan
 7 premium for the Medicare Prescription
 8 Drug plan with the lowest monthly plan
 9 premium in the area that the beneficiary
 10 resides’ for ‘the amount of such monthly na-
 11 tional average premium’, but only if there
 12 is no Medicare Prescription Drug plan of-
 13 fered in the area in which the individual re-
 14 sides that has a monthly plan premium for
 15 the year that is equal to or less than the
 16 monthly national average premium (as
 17 computed under section 1860D–15) for the
 18 area for the year;

19 “(B) the annual deductible applicable under
 20 section 1860D–6(c)(1) in a year shall be reduced
 21 to \$0;

22 “(C) section 1860D–6(c)(2) shall be applied
 23 by substituting ‘2.5 percent’ for ‘50 percent’ each
 24 place it appears;

1 “(D) such individual shall be responsible for
 2 cost-sharing for the cost of any covered drug pro-
 3 vided in the year (after the individual has
 4 reached the initial coverage limit described in
 5 section 1860D–6(c)(3) and before the individual
 6 has reached the annual out-of-pocket limit under
 7 section 1860D–6(c)(4)(A)), that is equal to 5.0
 8 percent; and

9 “(E) section 1860D–6(c)(4)(A) shall be ap-
 10 plied by substituting ‘2.5 percent’ for ‘10 per-
 11 cent’.

12 *In no case may the application of subparagraph (A)*
 13 *result in a monthly beneficiary obligation that is*
 14 *below 0.*

15 “(2) *FULL PREMIUM SUBSIDY AND REDUCTION*
 16 *OF COST-SHARING FOR SPECIFIED LOW INCOME MEDI-*
 17 *CARE BENEFICIARIES AND QUALIFYING INDIVID-*
 18 *UALS.—In the case of a specified low income medicare*
 19 *beneficiary (as defined in paragraph (4)(B)) or a*
 20 *qualifying individual (as defined in paragraph*
 21 *(4)(C))—*

22 “(A) section 1860D–17 shall be applied—

23 “(i) in subsection (c), by substituting
 24 ‘0 percent’ for the applicable percent that

1 *would otherwise apply under such sub-*
2 *section; and*

3 “(ii) in subsection (a)(3)(B), by sub-
4 stituting ‘the amount of the monthly plan
5 premium for the Medicare Prescription
6 Drug plan with the lowest monthly plan
7 premium in the area that the beneficiary
8 resides’ for ‘the amount of such monthly na-
9 tional average premium’, but only if there
10 is no Medicare Prescription Drug plan of-
11 fered in the area in which the individual re-
12 sides that has a monthly plan premium for
13 the year that is equal to or less than the
14 monthly national average premium (as
15 computed under section 1860D–15) for the
16 area for the year;

17 “(B) the annual deductible applicable under
18 section 1860D–6(c)(1) in a year shall be reduced
19 to \$0;

20 “(C) section 1860D–6(c)(2) shall be applied
21 by substituting ‘5.0 percent’ for ‘50 percent’ each
22 place it appears;

23 “(D) such individual shall be responsible for
24 cost-sharing for the cost of any covered drug pro-
25 vided in the year (after the individual has

reached the initial coverage limit described in section 1860D–6(c)(3) and before the individual has reached the annual out-of-pocket limit under section 1860D–6(c)(4)(A)), that is equal to 10.0 percent; and

“(E) section 1860D–6(c)(4)(A) shall be applied by substituting ‘2.5 percent’ for ‘10 percent’.

In no case may the application of subparagraph (A) result in a monthly beneficiary obligation that is below 0.

“(3) SLIDING SCALE PREMIUM SUBSIDY AND REDUCTION OF COST-SHARING FOR SUBSIDY-ELIGIBLE INDIVIDUALS.—

“(A) IN GENERAL.—In the case of a subsidy-eligible individual (as defined in paragraph (4)(D))—

“(i) section 1860D–17 shall be applied—

“(I) in subsection (c), by substituting ‘subsidy percent’ for the applicable percentage that would otherwise apply under such subsection; and

“(II) in subparagraphs (A) and (B) of subsection (a)(3), by sub-

1 *stituting ‘the amount of the monthly*
 2 *plan premium for the Medicare Pre-*
 3 *scription Drug plan with the lowest*
 4 *monthly plan premium in the area*
 5 *that the beneficiary resides’ for ‘the*
 6 *amount of such monthly national aver-*
 7 *age premium’, but only if there is no*
 8 *Medicare Prescription Drug plan of-*
 9 *fered in the area in which the indi-*
 10 *vidual resides that has a monthly plan*
 11 *premium for the year that is equal to*
 12 *or less than the monthly national aver-*
 13 *age premium (as computed under sec-*
 14 *tion 1860D–15) for the area for the*
 15 *year; and*

16 *“(ii) the annual deductible applicable*
 17 *under section 1860D–6(c)(1)—*

18 *“(I) for 2006, shall be reduced to*
 19 *\$50; and*

20 *“(II) for a subsequent year, shall*
 21 *be reduced to the amount specified*
 22 *under this clause for the previous year*
 23 *increased by the percentage specified in*
 24 *section 1860D–6(c)(5) for the year in-*
 25 *volved;*

1 “(iii) section 1860D–6(c)(2) shall be
2 applied by substituting ‘10.0 percent’ for
3 ‘50 percent’ each place it appears;

4 “(iv) such individual shall be respon-
5 sible for cost-sharing for the cost of any cov-
6 ered drug provided in the year (after the in-
7 dividual has reached the initial coverage
8 limit described in section 1860D–6(c)(3)
9 and before the individual has reached the
10 annual out-of-pocket limit under section
11 1860D–6(c)(4)(A)), that is equal to 20.0
12 percent; and

13 “(v) such individual shall be respon-
14 sible for the cost-sharing described in section
15 1860D–6(c)(4)(A).

16 *In no case may the application of clause (i) re-*
17 *sult in a monthly beneficiary obligation that is*
18 *below 0.*

19 “(B) *SUBSIDY PERCENT DEFINED.*—*For*
20 *purposes of subparagraph (A)(i), the term ‘sub-*
21 *sidy percent’ means, with respect to a State, a*
22 *percent determined on a linear sliding scale*
23 *ranging from—*

24 “(i) 0 percent with respect to a sub-
25 sidy-eligible individual residing in the

1 *State whose income does not exceed 135 per-*
 2 *cent of the poverty line; to*

3 “(ii) *the highest percentage that would*
 4 *otherwise apply under section 1860D–17 in*
 5 *the service area in which the subsidy-eligible*
 6 *individual resides, in the case of a subsidy-*
 7 *eligible individual residing in the State*
 8 *whose income equals 160 percent of the pov-*
 9 *erty line.*

10 “(4) *DEFINITIONS.—In this part:*

11 “(A) *QUALIFIED MEDICARE BENEFICIARY.—*
 12 *Subject to subparagraph (H), the term ‘qualified*
 13 *medicare beneficiary’ means an individual*
 14 *who—*

15 “(i) *is enrolled under this part, includ-*
 16 *ing an individual who is enrolled under a*
 17 *MedicareAdvantage plan;*

18 “(ii) *is eligible for medicare cost-shar-*
 19 *ing described in section 1905(p)(3) under*
 20 *the State plan under title XIX (or under a*
 21 *waiver of such plan), on the basis of being*
 22 *described in section 1905(p)(1), as deter-*
 23 *mined under such plan (or under a waiver*
 24 *of plan); and*

25 “(iii) *is not—*

1 “(I) a specified low-income medi-
2 care beneficiary;

3 “(II) a qualifying individual; or

4 “(III) a dual eligible individual.

5 “(B) SPECIFIED LOW INCOME MEDICARE
6 BENEFICIARY.—Subject to subparagraph (H), the
7 term ‘specified low income medicare beneficiary’
8 means an individual who—

9 “(i) is enrolled under this part, includ-
10 ing an individual who is enrolled under a
11 MedicareAdvantage plan;

12 “(ii) is eligible for medicare cost-shar-
13 ing described in section 1905(p)(3)(A)(ii)
14 under the State plan under title XIX (or
15 under a waiver of such plan), on the basis
16 of being described in section
17 1902(a)(10)(E)(iii), as determined under
18 such plan (or under a waiver of plan); and

19 “(iii) is not—

20 “(I) a qualified medicare bene-
21 ficiary;

22 “(II) a qualifying individual; or

23 “(III) a dual eligible individual.

1 “(C) *QUALIFYING INDIVIDUAL*.—Subject to
 2 subparagraph (H), the term ‘qualifying indi-
 3 vidual’ means an individual who—

4 “(i) is enrolled under this part, includ-
 5 ing an individual who is enrolled under a
 6 MedicareAdvantage plan;

7 “(ii) is eligible for medicare cost-shar-
 8 ing described in section 1905(p)(3)(A)(ii)
 9 under the State plan under title XIX (or
 10 under a waiver of such plan), on the basis
 11 of being described in section
 12 1902(a)(10)(E)(iv) (without regard to any
 13 termination of the application of such sec-
 14 tion under title XIX), as determined under
 15 such plan (or under a waiver of such plan);
 16 and

17 “(iii) is not—

18 “(I) a qualified medicare bene-
 19 ficiary;

20 “(II) a specified low-income medi-
 21 care beneficiary; or

22 “(III) a dual eligible individual.

23 “(D) *SUBSIDY-ELIGIBLE INDIVIDUAL*.—Sub-
 24 ject to subparagraph (H), the term ‘subsidy-eli-
 25 ble individual’ means an individual—

1 “(i) who is enrolled under this part,
 2 including an individual who is enrolled
 3 under a Medicare Advantage plan;

4 “(ii) whose income is less than 160
 5 percent of the poverty line; and

6 “(iii) who is not—

7 “(I) a qualified medicare bene-
 8 ficiary;

9 “(II) a specified low-income medi-
 10 care beneficiary;

11 “(III) a qualifying individual; or

12 “(IV) a dual eligible individual.

13 “(E) DUAL ELIGIBLE INDIVIDUAL.—

14 “(i) IN GENERAL.—The term ‘dual eli-
 15 gible individual’ means an individual who
 16 is—

17 “(I) enrolled under title XIX or
 18 under a waiver under section 1115 of
 19 the requirements of such title for med-
 20 ical assistance that is not less than the
 21 medical assistance provided to an indi-
 22 vidual described in section
 23 1902(a)(10)(A)(i) and includes covered
 24 outpatient drugs (as such term is de-
 25 fined for purposes of section 1927); and

1 “(II) entitled to benefits under
2 part A and enrolled under part B.

3 “(ii) INCLUSION OF MEDICALLY
4 NEEDY.—Such term includes an individual
5 described in section 1902(a)(10)(C).

6 “(F) POVERTY LINE.—The term ‘poverty
7 line’ has the meaning given such term in section
8 673(2) of the Community Services Block Grant
9 Act (42 U.S.C. 9902(2)), including any revision
10 required by such section.

11 “(G) ELIGIBILITY DETERMINATIONS.—Be-
12 ginning on November 1, 2005, the determination
13 of whether an individual residing in a State is
14 an individual described in subparagraph (A),
15 (B), (C), (D), or (E) and, for purposes of para-
16 graph (3), the amount of an individual’s income,
17 shall be determined under the State medicaid
18 plan for the State under section 1935(a). In the
19 case of a State that does not operate such a med-
20 icaid plan (either under title XIX or under a
21 statewide waiver granted under section 1115),
22 such determination shall be made under arrange-
23 ments made by the Administrator.

24 “(H) NONAPPLICATION TO DUAL ELIGIBLE
25 INDIVIDUALS AND TERRITORIAL RESIDENTS.—In

1 *the case of an individual who is a dual eligible*
 2 *individual or an individual who is not a resi-*
 3 *dent of the 50 States or the District of*
 4 *Columbia—*

5 *“(i) the subsidies provided under this*
 6 *section shall not apply; and*

7 *“(ii) in the case of such an individual*
 8 *who is not a resident of the 50 States or the*
 9 *District of Columbia, such individual may*
 10 *be provided with medical assistance for cov-*
 11 *ered outpatient drugs (as such term is de-*
 12 *finied for purposes of section 1927) in ac-*
 13 *cordance with section 1935 under the State*
 14 *medicaid program under title XIX.*

15 *“(I) UPDATE OF ASSET OR RESOURCE*
 16 *TEST.—With respect to eligibility determinations*
 17 *for premium and cost-sharing subsidies under*
 18 *this section that are made on or after January*
 19 *1, 2009, such determinations shall be made (to*
 20 *the extent a State, as of such date, has not al-*
 21 *ready eliminated the application of an asset or*
 22 *resource test under section 1905(p)(1)(C)) in ac-*
 23 *cordance with the following:*

24 *“(i) SELF-DECLARATION OF VALUE.—*

1 “(I) *IN GENERAL.*—A State shall
2 *permit an individual applying for*
3 *such subsidies to declare and certify by*
4 *signature under penalty of perjury on*
5 *the application form that the value of*
6 *the individual’s assets or resources (or*
7 *the combined value of the individual’s*
8 *assets or resources and the assets or re-*
9 *sources of the individual’s spouse), as*
10 *determined under section 1613 for pur-*
11 *poses of the supplemental security in-*
12 *come program, does not exceed \$10,000*
13 *(\$20,000 in the case of the combined*
14 *value of the individual’s assets or re-*
15 *sources and the assets or resources of*
16 *the individual’s spouse).*

17 “(II) *ANNUAL ADJUSTMENT.*—Be-
18 *ginning on January 1, 2010, and for*
19 *each subsequent year, the dollar*
20 *amounts specified in subclause (I) for*
21 *the preceding year shall be increased*
22 *by the percentage increase in the Con-*
23 *sumer Price Index for all urban con-*
24 *sumers (U.S. urban average) for the*

1 12-month period ending with June of
2 the previous year.

3 “(ii) *METHODOLOGY FLEXIBILITY.*—
4 *Nothing in clause (i) shall be construed as*
5 *prohibiting a State in making eligibility*
6 *determinations for premium and cost-shar-*
7 *ing subsidies under this section from using*
8 *asset or resource methodologies that are less*
9 *restrictive than the methodologies used*
10 *under 1613 for purposes of the supplemental*
11 *security income program.*

12 “(J) *DEVELOPMENT OF MODEL DECLARA-*
13 *TION FORM.*—*The Secretary shall—*

14 “(i) *develop a model, simplified appli-*
15 *cation form for individuals to use in mak-*
16 *ing a self-declaration of assets or resources*
17 *in accordance with subparagraph (I)(i);*
18 *and*

19 “(ii) *provide such form to States and,*
20 *for purposes of outreach under section 1144,*
21 *the Commissioner of Social Security.”.*

22 “(b) *RULES IN APPLYING COST-SHARING SUB-*
23 *SIDIES.*—*Nothing in this section shall be construed as pre-*
24 *venting an eligible entity offering a Medicare Prescription*
25 *Drug plan or a MedicareAdvantage organization offering*

1 *a MedicareAdvantage plan from waiving or reducing the*
 2 *amount of the deductible or other cost-sharing otherwise ap-*
 3 *plicable pursuant to section 1860D–6(a)(2).*

4 “(c) *ADMINISTRATION OF SUBSIDY PROGRAM.—The*
 5 *Administrator shall establish a process whereby, in the case*
 6 *of an individual eligible for a cost-sharing subsidy under*
 7 *subsection (a) who is enrolled in a Medicare Prescription*
 8 *Drug plan or a MedicareAdvantage plan—*

9 “(1) *the Administrator provides for a notifica-*
 10 *tion of the eligible entity or MedicareAdvantage orga-*
 11 *nization involved that the individual is eligible for a*
 12 *cost-sharing subsidy and the amount of the subsidy*
 13 *under such subsection;*

14 “(2) *the entity or organization involved reduces*
 15 *the cost-sharing otherwise imposed by the amount of*
 16 *the applicable subsidy and submits to the Adminis-*
 17 *trator information on the amount of such reduction;*
 18 *and*

19 “(3) *the Administrator periodically and on a*
 20 *timely basis reimburses the entity or organization for*
 21 *the amount of such reductions.*

22 *The reimbursement under paragraph (3) may be computed*
 23 *on a capitated basis, taking into account the actuarial*
 24 *value of the subsidies and with appropriate adjustments to*
 25 *reflect differences in the risks actually involved.*

1 “(d) *RELATION TO MEDICAID PROGRAM.*—For provi-
 2 sions providing for eligibility determinations and addi-
 3 tional Federal payments for expenditures related to pro-
 4 viding prescription drug coverage for dual eligible individ-
 5 uals and territorial residents under the medicaid program,
 6 see section 1935.

7 “REINSURANCE PAYMENTS FOR EXPENSES INCURRED IN
 8 PROVIDING PRESCRIPTION DRUG COVERAGE ABOVE
 9 THE ANNUAL OUT-OF-POCKET THRESHOLD

10 “SEC. 1860D–20. (a) *REINSURANCE PAYMENTS.*—

11 “(1) *IN GENERAL.*—Subject to section 1860D–
 12 21(b), the Administrator shall provide in accordance
 13 with this section for payment to a qualifying entity
 14 of the reinsurance payment amount (as specified in
 15 subsection (c)(1)) for costs incurred by the entity in
 16 providing prescription drug coverage for a qualifying
 17 covered individual after the individual has reached
 18 the annual out-of-pocket threshold specified in section
 19 1860D–6(c)(4)(B) for the year.

20 “(2) *BUDGET AUTHORITY.*—This section con-
 21 stitutes budget authority in advance of appropria-
 22 tions Acts and represents the obligation of the Admin-
 23 istrator to provide for the payment of amounts pro-
 24 vided under this section.

25 “(b) *NOTIFICATION OF SPENDING UNDER THE PLAN*
 26 *FOR COSTS INCURRED IN PROVIDING PRESCRIPTION DRUG*

1 *COVERAGE ABOVE THE ANNUAL OUT-OF-POCKET THRESH-*
 2 *OLD.—*

3 “(1) *IN GENERAL.—Each qualifying entity shall*
 4 *notify the Administrator of the following with respect*
 5 *to a qualifying covered individual for a coverage*
 6 *year:*

7 “(A) *TOTAL ACTUAL COSTS.—The total*
 8 *amount (if any) of costs that the qualifying enti-*
 9 *ty incurred in providing prescription drug cov-*
 10 *erage for the individual in the year after the in-*
 11 *dividual had reached the annual out-of-pocket*
 12 *threshold specified in section 1860D–6(c)(4)(B)*
 13 *for the year.*

14 “(B) *AMOUNTS RESULTING IN ACTUAL*
 15 *COSTS.—With respect to the total amount under*
 16 *subparagraph (A) for the year—*

17 “(i) *the aggregate amount of payments*
 18 *made by the entity to pharmacies and other*
 19 *entities with respect to such coverage for*
 20 *such enrollees; and*

21 “(ii) *the aggregate amount of dis-*
 22 *counts, direct or indirect subsidies, rebates,*
 23 *or other price concessions or direct or indi-*
 24 *rect remunerations made to the entity with*
 25 *respect to such coverage for such enrollees.*

1 “(2) *CERTAIN EXPENSES NOT INCLUDED.*—*The*
2 *amount under paragraph (1)(A) may not include—*

3 “(A) *administrative expenses incurred in*
4 *providing the coverage described in paragraph*
5 *(1)(A);*

6 “(B) *amounts expended on providing addi-*
7 *tional prescription drug coverage pursuant to*
8 *section 1860D–6(a)(2); or*

9 “(C) *discounts, direct or indirect subsidies,*
10 *rebates, or other price concessions or direct or in-*
11 *direct remunerations made to the entity with re-*
12 *spect to coverage described in paragraph (1)(A).*

13 “(3) *RESTRICTION ON USE OF INFORMATION.*—
14 *The restriction specified in section 1860D–16(b)(7)(B)*
15 *shall apply to information disclosed or obtained pur-*
16 *suant to the provisions of this section.*

17 “(c) *REINSURANCE PAYMENT AMOUNT.*—

18 “(1) *IN GENERAL.*—*The reinsurance payment*
19 *amount under this subsection for a qualifying covered*
20 *individual for a coverage year is an amount equal to*
21 *80 percent (or 65 percent with respect to a qualifying*
22 *covered individual described in subsection (e)(2)(D))*
23 *of the allowable costs (as specified in paragraph (2))*
24 *incurred by the qualifying entity with respect to the*
25 *individual and year.*

1 “(2) *ESTABLISHMENT OF ALLOWABLE COSTS.*—

2 *In the case of a qualifying entity that has incurred*
 3 *costs described in subsection (b)(1)(A) with respect to*
 4 *a qualifying covered individual for a coverage year,*
 5 *the Administrator shall establish the allowable costs*
 6 *for the individual and year. Such allowable costs*
 7 *shall be equal to the amount described in such sub-*
 8 *section for the individual and year.*

9 “(d) *PAYMENT METHODS.*—

10 “(1) *IN GENERAL.*—*Payments under this section*
 11 *shall be based on such a method as the Administrator*
 12 *determines. The Administrator may establish a pay-*
 13 *ment method by which interim payments of amounts*
 14 *under this section are made during a year based on*
 15 *the Administrator’s best estimate of amounts that will*
 16 *be payable after obtaining all of the information.*

17 “(2) *SOURCE OF PAYMENTS.*—*Payments under*
 18 *this section shall be made from the Prescription Drug*
 19 *Account.*

20 “(e) *DEFINITIONS.*—*In this section:*

21 “(1) *COVERAGE YEAR.*—*The term ‘coverage year’*
 22 *means a calendar year in which covered drugs are*
 23 *dispensed if a claim for payment is made under the*
 24 *plan for such drugs, regardless of when the claim is*
 25 *paid.*

1 “(2) *QUALIFYING COVERED INDIVIDUAL.*—*The*
 2 *term ‘qualifying covered individual’ means an indi-*
 3 *vidual who—*

4 “(A) *is enrolled in this part and in a Medi-*
 5 *care Prescription Drug plan;*

6 “(B) *is enrolled in this part and in a*
 7 *MedicareAdvantage plan (except for an MSA*
 8 *plan or a private fee-for-service plan that does*
 9 *not provide qualified prescription drug cov-*
 10 *erage);*

11 “(C) *is eligible for, but not enrolled in, the*
 12 *program under this part, and is covered under*
 13 *a qualified retiree prescription drug plan; or*

14 “(D) *is eligible for, but not enrolled in, the*
 15 *program under this part, and is covered under*
 16 *a qualified State pharmaceutical assistance pro-*
 17 *gram.*

18 “(3) *QUALIFYING ENTITY.*—*The term ‘qualifying*
 19 *entity’ means any of the following that has entered*
 20 *into an agreement with the Administrator to provide*
 21 *the Administrator with such information as may be*
 22 *required to carry out this section:*

23 “(A) *An eligible entity offering a Medicare*
 24 *Prescription Drug plan under this part.*

1 “(B) A MedicareAdvantage organization of-
 2 fering a MedicareAdvantage plan under part C
 3 (except for an MSA plan or a private fee-for-
 4 service plan that does not provide qualified pre-
 5 scription drug coverage).

6 “(C) The sponsor of a qualified retiree pre-
 7 scription drug plan.

8 “(D) A State offering a qualified State
 9 pharmaceutical assistance program.

10 “(4) QUALIFIED RETIREE PRESCRIPTION DRUG
 11 PLAN.—

12 “(A) IN GENERAL.—The term ‘qualified re-
 13 tiree prescription drug plan’ means employment-
 14 based retiree health coverage if, with respect to a
 15 qualifying covered individual who is covered
 16 under the plan, the following requirements are
 17 met:

18 “(i) ATTESTATION OF ACTUARIAL
 19 VALUE OF COVERAGE.—The sponsor of the
 20 plan shall, annually or at such other time
 21 as the Administrator may require, provide
 22 the Administrator an attestation, in accord-
 23 ance with the procedures established under
 24 section 1860D–6(f), that the actuarial value
 25 of prescription drug coverage under the

1 *plan is at least equal to the actuarial value*
 2 *of standard prescription drug coverage.*

3 “(ii) *AUDITS.*—*The sponsor of the*
 4 *plan, or an administrator of the plan des-*
 5 *ignated by the sponsor, shall maintain (and*
 6 *afford the Administrator access to) such*
 7 *records as the Administrator may require*
 8 *for purposes of audits and other oversight*
 9 *activities necessary to ensure the adequacy*
 10 *of prescription drug coverage and the accu-*
 11 *racy of payments made under this part to*
 12 *and by the plan.*

13 “(B) *EMPLOYMENT-BASED RETIREE*
 14 *HEALTH COVERAGE.*—*The term ‘employment-*
 15 *based retiree health coverage’ means health in-*
 16 *surance or other coverage, whether provided by*
 17 *voluntary insurance coverage or pursuant to*
 18 *statutory or contractual obligation, of health care*
 19 *costs for retired individuals (or for such individ-*
 20 *uals and their spouses and dependents) based on*
 21 *their status as former employees or labor union*
 22 *members.*

23 “(5) *QUALIFIED STATE PHARMACEUTICAL AS-*
 24 *SISTANCE PROGRAM.*—

1 “(A) *IN GENERAL.*—The term ‘qualified
 2 *State pharmaceutical assistance program*’ means
 3 *a State pharmaceutical assistance program if,*
 4 *with respect to a qualifying covered individual*
 5 *who is covered under the program, the following*
 6 *requirements are met:*

7 “(i) *ASSURANCE.*—The State offering
 8 *the program shall, annually or at such*
 9 *other times as the Administrator may re-*
 10 *quire, provide the Administrator an attesta-*
 11 *tion that, in accordance with the procedures*
 12 *established under section 1860D–6(f),*
 13 *that—*

14 “(I) *the actuarial value of pre-*
 15 *scription drug coverage under the pro-*
 16 *gram is at least equal to the actuarial*
 17 *value of standard prescription drug*
 18 *coverage; and*

19 “(II) *the actuarial value of sub-*
 20 *sidies to individuals provided under*
 21 *the program are at least equal to the*
 22 *actuarial value of the subsidies that*
 23 *would apply under section 1860D–19*
 24 *if the individual was enrolled under*

1 *this part rather than under the pro-*
 2 *gram.*

3 “(ii) *DISCLOSURE OF INFORMATION.*—
 4 *The State complies with the requirements*
 5 *described in clauses (i) and (ii) of section*
 6 *1860D–16(b)(7)(A).*

7 “(B) *STATE PHARMACEUTICAL ASSISTANCE*
 8 *PROGRAM.*—*For purposes of subparagraph (A),*
 9 *the term ‘State pharmaceutical assistance pro-*
 10 *gram’ means a program—*

11 “(i) *that is in operation as of the date*
 12 *of enactment of the Prescription Drug and*
 13 *Medicare Improvement Act of 2003;*

14 “(ii) *that is sponsored and financed by*
 15 *a State; and*

16 “(iii) *that provides coverage for out-*
 17 *patient drugs for individuals in the State*
 18 *who meet income- and resource-related*
 19 *qualifications specified under such program.*

20 “(6) *SPONSOR.*—*The term ‘sponsor’ means a*
 21 *plan sponsor, as defined in section 3(16)(B) of the*
 22 *Employee Retirement Income Security Act of 1974.*

23 “(f) *DISTRIBUTION OF REINSURANCE PAYMENT*
 24 *AMOUNTS.*—

1 “(1) *IN GENERAL.*—Any sponsor meeting the re-
2 quirements of subsection (e)(3) with respect to a quar-
3 ter in a calendar year, but which is not an employer,
4 shall distribute the reinsurance payments received for
5 such quarter under subsection (c) to the employers
6 contributing to the qualified retiree prescription drug
7 plan maintained by such sponsor during that quar-
8 ter, in the manner described in paragraphs (2) and
9 (3).

10 “(2) *ALLOCATION.*—The reinsurance payments to
11 be distributed pursuant to paragraph (1) shall be al-
12 located proportionally among all employers who con-
13 tribute to the plan during the quarter with respect to
14 which the payments are received. The share allocated
15 to each employer contributing to the plan during a
16 quarter shall be determined by multiplying the total
17 reinsurance payments received by the sponsor for the
18 quarter by a fraction, the numerator of which is the
19 total contributions made by an employer for that
20 quarter, and the denominator of which is the total
21 contributions required to be made to the plan by all
22 employers for that quarter. Any share allocated to an
23 employer required to contribute for a quarter who
24 does not make the contributions required for that

1 *quarter on or before the date due shall be retained by*
 2 *the sponsor for the benefit of the plan as a whole.*

3 “(3) *TIMING.—Reinsurance payments required*
 4 *to be distributed to employers pursuant to this sub-*
 5 *section shall be distributed as soon as practicable*
 6 *after received by the sponsor, but in no event later*
 7 *than the end of the quarter immediately following the*
 8 *quarter in which such reinsurance payments are re-*
 9 *ceived by the sponsor.*

10 “(4) *REGULATIONS.—The Secretary shall pro-*
 11 *mulgate regulations providing that any sponsor sub-*
 12 *ject to the requirements of this subsection who fails to*
 13 *meet such requirements shall not be eligible for a pay-*
 14 *ment under this section.*

15 “*DIRECT SUBSIDY FOR SPONSOR OF A QUALIFIED RETIREE*
 16 *PRESCRIPTION DRUG PLAN FOR PLAN ENROLLEES EL-*
 17 *IGIBLE FOR, BUT NOT ENROLLED IN, THIS PART*

18 “*SEC. 1860D–21. (a) DIRECT SUBSIDY.—*

19 “(1) *IN GENERAL.—The Administrator shall pro-*
 20 *vide for the payment to a sponsor of a qualified re-*
 21 *tiree prescription drug plan (as defined in section*
 22 *1860D–20(e)(4)) for each qualifying covered indi-*
 23 *vidual (described in subparagraph (C) of section*
 24 *1860D–20(e)(2)) enrolled in the plan for each month*
 25 *for which such individual is so enrolled.*

26 “(2) *AMOUNT OF PAYMENT.—*

1 “(A) *IN GENERAL.*—*The amount of the pay-*
 2 *ment under paragraph (1) shall be an amount*
 3 *equal to the direct subsidy percent determined*
 4 *for the year of the monthly national average pre-*
 5 *mium for the area for the year (determined*
 6 *under section 1860D–15), as adjusted using the*
 7 *risk adjusters that apply to the standard pre-*
 8 *scription drug coverage published under section*
 9 *1860D–11.*

10 “(B) *DIRECT SUBSIDY PERCENT.*—*For pur-*
 11 *poses of subparagraph (A), the term ‘direct sub-*
 12 *sidy percent’ means the percentage equal to—*

13 “(i) *100 percent; minus*

14 “(ii) *the applicable percent for the year*
 15 *(as determined under section 1860D–17(c)).*

16 “(b) *PAYMENT METHODS.*—

17 “(1) *IN GENERAL.*—*Payments under this section*
 18 *shall be based on such a method as the Administrator*
 19 *determines. The Administrator may establish a pay-*
 20 *ment method by which interim payments of amounts*
 21 *under this section are made during a year based on*
 22 *the Administrator’s best estimate of amounts that will*
 23 *be payable after obtaining all of the information.*

1 “(2) *SOURCE OF PAYMENTS.*—*Payments under*
 2 *this section shall be made from the Prescription Drug*
 3 *Account.*

4 “*DIRECT SUBSIDIES FOR QUALIFIED STATE OFFERING A*
 5 *STATE PHARMACEUTICAL ASSISTANCE PROGRAM FOR*
 6 *PROGRAM ENROLLEES ELIGIBLE FOR, BUT NOT EN-*
 7 *ROLLED IN, THIS PART*

8 “*SEC. 1860D–22. (a) DIRECT SUBSIDY.*—

9 “*(1) IN GENERAL.*—*The Administrator shall pro-*
 10 *vide for the payment to a State offering a qualified*
 11 *State pharmaceutical assistance program (as defined*
 12 *in section 1860D–20(e)(6)) for each qualifying cov-*
 13 *ered individual (described in subparagraph (D) of*
 14 *section 1860D–(e)(2)) enrolled in the program for*
 15 *each month for which such individual is so enrolled.*

16 “*(2) AMOUNT OF PAYMENT.*—

17 “*(A) IN GENERAL.*—*The amount of the pay-*
 18 *ment under paragraph (1) shall be an amount*
 19 *equal to the amount of payment for the area and*
 20 *year made under section 1860D–21(a)(2).*

21 “*(b) ADDITIONAL SUBSIDY.*—

22 “*(1) IN GENERAL.*—*The Administrator shall pro-*
 23 *vide for the payment to a State offering a qualified*
 24 *State pharmaceutical program (as defined in section*
 25 *1860D–20(e)(6)) for each applicable low-income indi-*

vidual enrolled in the program for each month for which such individual is so enrolled.

“(2) *AMOUNT OF PAYMENT.*—

“(A) *IN GENERAL.*—The amount of the payment under paragraph (1) shall be the amount the Administrator estimates would have been made to an entity or organization under section 1860D–19 with respect to the applicable low-income individual if such individual was enrolled in this part and under a Medicare Prescription Drug plan or a Medicare Advantage plan.

“(B) *MAXIMUM PAYMENTS.*—In no case may the amount of the payment determined under subparagraph (A) with respect to an applicable low-income individual exceed, as estimated by the Administrator, the average amounts made in a year under section 1860D–19 on behalf of an eligible beneficiary enrolled under this part with income that is the same as the income of the applicable low-income individual.

“(3) *APPLICABLE LOW-INCOME INDIVIDUAL.*—

For purposes of this subsection, the term ‘applicable low-income individual’ means an individual who is both—

1 “(A) a qualifying covered individual (de-
 2 scribed in subparagraph (D) of section 1860D-
 3 (e)(2)); and

4 “(B) a qualified medicare beneficiary, a
 5 specified low income medicare beneficiary, or a
 6 subsidy-eligible individual, as such terms are de-
 7 fined in section 1860D-19(a)(4).

8 “(c) *PAYMENT METHODS.*—

9 “(1) *IN GENERAL.*—Payments under this section
 10 shall be based on such a method as the Administrator
 11 determines. The Administrator may establish a pay-
 12 ment method by which interim payments of amounts
 13 under this section are made during a year based on
 14 the Administrator’s best estimate of amounts that will
 15 be payable after obtaining all of the information.

16 “(2) *SOURCE OF PAYMENTS.*—Payments under
 17 this section shall be made from the Prescription Drug
 18 Account.

19 “(d) *CONSTRUCTION.*—Nothing in this section or sec-
 20 tion 1860D-20 shall effect the provisions of section 1860D-
 21 26(b).

22 “Subpart 3—Miscellaneous Provisions

23 “*PRESCRIPTION DRUG ACCOUNT IN THE FEDERAL*
 24 *SUPPLEMENTARY MEDICAL INSURANCE TRUST FUND*

25 “*SEC. 1860D-25. (a) ESTABLISHMENT.*—

1 “(1) *IN GENERAL.*—*There is created within the*
 2 *Federal Supplementary Medical Insurance Trust*
 3 *Fund established by section 1841 an account to be*
 4 *known as the ‘Prescription Drug Account’ (in this*
 5 *section referred to as the ‘Account’).*

6 “(2) *FUNDS.*—*The Account shall consist of such*
 7 *gifts and bequests as may be made as provided in sec-*
 8 *tion 201(i)(1), and such amounts as may be deposited*
 9 *in, or appropriated to, the Account as provided in*
 10 *this part.*

11 “(3) *SEPARATE FROM REST OF TRUST FUND.*—
 12 *Funds provided under this part to the Account shall*
 13 *be kept separate from all other funds within the Fed-*
 14 *eral Supplementary Medical Insurance Trust Fund.*

15 “(b) *PAYMENTS FROM ACCOUNT.*—

16 “(1) *IN GENERAL.*—*The Managing Trustee shall*
 17 *pay from time to time from the Account such*
 18 *amounts as the Secretary certifies are necessary to*
 19 *make payments to operate the program under this*
 20 *part, including—*

21 “(A) *payments to eligible entities under sec-*
 22 *tion 1860D–16;*

23 “(B) *payments under 1860D–19 for low-in-*
 24 *come subsidy payments for cost-sharing;*

1 “(C) *reinsurance payments under section*
2 *1860D–20;*

3 “(D) *payments to sponsors of qualified re-*
4 *tiree prescription drug plans under section*
5 *1860D–21;*

6 “(E) *payments to MedicareAdvantage orga-*
7 *nizations for the provision of qualified prescrip-*
8 *tion drug coverage under section 1858A(c); and*

9 “(F) *payments with respect to administra-*
10 *tive expenses under this part in accordance with*
11 *section 201(g).*

12 “(2) *TREATMENT IN RELATION TO PART B PRE-*
13 *MIUM.—Amounts payable from the Account shall not*
14 *be taken into account in computing actuarial rates or*
15 *premium amounts under section 1839.*

16 “(c) *APPROPRIATIONS TO COVER BENEFITS AND AD-*
17 *MINISTRATIVE COSTS.—There are appropriated to the Ac-*
18 *count in a fiscal year, out of any moneys in the Treasury*
19 *not otherwise appropriated, an amount equal to the pay-*
20 *ments and transfers made from the Account in the year.*

21 “OTHER RELATED PROVISIONS

22 “SEC. 1860D–26. (a) *RESTRICTION ON ENROLLMENT*
23 *IN A MEDICARE PRESCRIPTION DRUG PLAN OFFERED BY*
24 *A SPONSOR OF EMPLOYMENT-BASED RETIREE HEALTH*
25 *COVERAGE.—*

1 “(1) *IN GENERAL.*—*In the case of a Medicare*
 2 *Prescription Drug plan offered by an eligible entity*
 3 *that is a sponsor (as defined in paragraph (5) of sec-*
 4 *tion 1860D–20(e)) of employment-based retiree health*
 5 *coverage (as defined in paragraph (4)(B) of such sec-*
 6 *tion), notwithstanding any other provision of this*
 7 *part and in accordance with regulations of the Ad-*
 8 *ministrator, the entity offering the plan may restrict*
 9 *the enrollment of eligible beneficiaries enrolled under*
 10 *this part to eligible beneficiaries who are enrolled in*
 11 *such coverage.*

12 “(2) *LIMITATION.*—*The sponsor of the employ-*
 13 *ment-based retiree health coverage described in para-*
 14 *graph (1) may not offer enrollment in the Medicare*
 15 *Prescription Drug plan described in such paragraph*
 16 *based on the health status of eligible beneficiaries en-*
 17 *rolled for such coverage.*

18 “(b) *COORDINATION WITH STATE PHARMACEUTICAL*
 19 *ASSISTANCE PROGRAMS.*—

20 “(1) *IN GENERAL.*—*An eligible entity offering a*
 21 *Medicare Prescription Drug plan, or a*
 22 *MedicareAdvantage organization offering a*
 23 *MedicareAdvantage plan (other than an MSA plan or*
 24 *a private fee-for-service plan that does not provide*
 25 *qualified prescription drug coverage), may enter into*

1 *an agreement with a State pharmaceutical assistance*
 2 *program described in paragraph (2) to coordinate the*
 3 *coverage provided under the plan with the assistance*
 4 *provided under the State pharmaceutical assistance*
 5 *program.*

6 “(2) *STATE PHARMACEUTICAL ASSISTANCE PRO-*
 7 *GRAM DESCRIBED.—For purposes of paragraph (1), a*
 8 *State pharmaceutical assistance program described in*
 9 *this paragraph is a program that has been established*
 10 *pursuant to a waiver under section 1115 or otherwise.*

11 “(c) *REGULATIONS TO CARRY OUT THIS PART.—*

12 “(1) *AUTHORITY FOR INTERIM FINAL REGULA-*
 13 *TIONS.—The Secretary may promulgate initial regu-*
 14 *lations implementing this part in interim final form*
 15 *without prior opportunity for public comment.*

16 “(2) *FINAL REGULATIONS.—A final regulation*
 17 *reflecting public comments must be published within*
 18 *1 year of the interim final regulation promulgated*
 19 *under paragraph (1).”.*

20 “(d) *WAIVER AUTHORITY.—The Secretary shall have*
 21 *authority similar to the waiver authority under section*
 22 *1857(i) to facilitate the offering of Medicare Prescription*
 23 *Drug plans by employer or other group health plans as part*
 24 *of employment-based retiree health coverage (as defined in*
 25 *section 1860D–20(d)(4)(B)), including the authority to es-*

1 *tablish separate premium amounts for enrollees in a Medi-*
 2 *care Prescription Drug plan by reason of such coverage.”.*

3 *(b) CONFORMING AMENDMENTS TO FEDERAL SUPPLE-*
 4 *MENTARY MEDICAL INSURANCE TRUST FUND.—Section*
 5 *1841 (42 U.S.C. 1395t) is amended—*

6 *(1) in the last sentence of subsection (a)—*

7 *(A) by striking “and” before “such*
 8 *amounts”; and*

9 *(B) by inserting before the period the fol-*
 10 *lowing: “, and such amounts as may be depos-*
 11 *ited in, or appropriated to, the Prescription*
 12 *Drug Account established by section 1860D–25”;*

13 *(2) in subsection (g), by inserting after “by this*
 14 *part,” the following: “the payments provided for*
 15 *under part D (in which case the payments shall be*
 16 *made from the Prescription Drug Account in the*
 17 *Trust Fund),”;*

18 *(3) in subsection (h), by inserting after*
 19 *“1840(d)” the following: “and sections 1860D–18 and*
 20 *1858A(e) (in which case the payments shall be made*
 21 *from the Prescription Drug Account in the Trust*
 22 *Fund),”;* and

23 *(4) in subsection (i), by inserting after “section*
 24 *1840(b)(1)” the following: “, sections 1860D–18 and*
 25 *1858A(e) (in which case the payments shall be made*

1 *from the Prescription Drug Account in the Trust*
 2 *Fund),”.*

3 (c) *CONFORMING REFERENCES TO PREVIOUS PART*
 4 *D.—Any reference in law (in effect before the date of enact-*
 5 *ment of this Act) to part D of title XVIII of the Social*
 6 *Security Act is deemed a reference to part F of such title*
 7 *(as in effect after such date).*

8 (d) *SUBMISSION OF LEGISLATIVE PROPOSAL.—Not*
 9 *later than 6 months after the date of the enactment of this*
 10 *Act, the Secretary shall submit to the appropriate commit-*
 11 *tees of Congress a legislative proposal providing for such*
 12 *technical and conforming amendments in the law as are*
 13 *required by the provisions of this Act.*

14 **SEC. 102. STUDY AND REPORT ON PERMITTING PART B**
 15 **ONLY INDIVIDUALS TO ENROLL IN MEDICARE**
 16 **VOLUNTARY PRESCRIPTION DRUG DELIVERY**
 17 **PROGRAM.**

18 (a) *STUDY.—The Administrator of the Center for*
 19 *Medicare Choices (as established under section 1808 of the*
 20 *Social Security Act, as added by section 301(a)) shall con-*
 21 *duct a study on the need for rules relating to permitting*
 22 *individuals who are enrolled under part B of title XVIII*
 23 *of the Social Security Act but are not entitled to benefits*
 24 *under part A of such title to buy into the medicare vol-*

1 untary prescription drug delivery program under part D
2 of such title (as so added).

3 (b) *REPORT*.—Not later than January 1, 2005, the Ad-
4 ministrator of the Center for Medicare Choices shall submit
5 a report to Congress on the study conducted under sub-
6 section (a), together with any recommendations for legisla-
7 tion that the Administrator determines to be appropriate
8 as a result of such study.

9 **SEC. 103. RULES RELATING TO MEDIGAP POLICIES THAT**
10 **PROVIDE PRESCRIPTION DRUG COVERAGE.**

11 (a) *RULES RELATING TO MEDIGAP POLICIES THAT*
12 *PROVIDE PRESCRIPTION DRUG COVERAGE*.—Section 1882
13 (42 U.S.C. 1395ss) is amended by adding at the end the
14 following new subsection:

15 “(v) *RULES RELATING TO MEDIGAP POLICIES THAT*
16 *PROVIDE PRESCRIPTION DRUG COVERAGE*.—

17 “(1) *PROHIBITION ON SALE, ISSUANCE, AND RE-*
18 *NEWAL OF POLICIES THAT PROVIDE PRESCRIPTION*
19 *DRUG COVERAGE TO PART D ENROLLEES*.—

20 “(A) *IN GENERAL*.—Notwithstanding any
21 other provision of law, on or after January 1,
22 2006, no medicare supplemental policy that pro-
23 vides coverage of expenses for prescription drugs
24 may be sold, issued, or renewed under this sec-

1 *tion to an individual who is enrolled under part*
 2 *D.*

3 “(B) *PENALTIES.*—*The penalties described*
 4 *in subsection (d)(3)(A)(ii) shall apply with re-*
 5 *spect to a violation of subparagraph (A).*

6 “(2) *ISSUANCE OF SUBSTITUTE POLICIES IF THE*
 7 *POLICYHOLDER OBTAINS PRESCRIPTION DRUG COV-*
 8 *ERAGE UNDER PART D.*—

9 “(A) *IN GENERAL.*—*The issuer of a medi-*
 10 *care supplemental policy—*

11 “(i) *may not deny or condition the*
 12 *issuance or effectiveness of a medicare sup-*
 13 *plemental policy that has a benefit package*
 14 *classified as ‘A’, ‘B’, ‘C’, ‘D’, ‘E’, ‘F’ (in-*
 15 *cluding the benefit package classified as ‘F’*
 16 *with a high deductible feature, as described*
 17 *in subsection (p)(11)), or ‘G’ (under the*
 18 *standards established under subsection*
 19 *(p)(2)) and that is offered and is available*
 20 *for issuance to new enrollees by such issuer;*

21 “(ii) *may not discriminate in the pric-*
 22 *ing of such policy, because of health status,*
 23 *claims experience, receipt of health care, or*
 24 *medical condition; and*

1 “(iii) may not impose an exclusion of
 2 benefits based on a pre-existing condition
 3 under such policy,
 4 in the case of an individual described in sub-
 5 paragraph (B) who seeks to enroll under the pol-
 6 icy during the open enrollment period established
 7 under section 1860D–2(b)(2) and who submits
 8 evidence that they meet the requirements under
 9 subparagraph (B) along with the application for
 10 such medicare supplemental policy.

11 “(B) *INDIVIDUAL DESCRIBED*.—An indi-
 12 vidual described in this subparagraph is an in-
 13 dividual who—

14 “(i) enrolls in the medicare prescrip-
 15 tion drug delivery program under part D;
 16 and

17 “(ii) at the time of such enrollment
 18 was enrolled and terminates enrollment in
 19 a medicare supplemental policy which has a
 20 benefit package classified as ‘H’, ‘I’, or ‘J’
 21 (including the benefit package classified as
 22 ‘J’ with a high deductible feature, as de-
 23 scribed in section 1882(p)(11)) under the
 24 standards referred to in subparagraph
 25 (A)(i) or terminates enrollment in a policy

1 to which such standards do not apply but
 2 which provides benefits for prescription
 3 drugs.

4 “(C) *ENFORCEMENT.*—The provisions of
 5 subparagraph (A) shall be enforced as though
 6 they were included in subsection (s).

7 “(3) *NOTICE REQUIRED TO BE PROVIDED TO*
 8 *CURRENT POLICYHOLDERS WITH PRESCRIPTION DRUG*
 9 *COVERAGE.*—No medicare supplemental policy of an
 10 issuer shall be deemed to meet the standards in sub-
 11 section (c) unless the issuer provides written notice
 12 during the 60-day period immediately preceding the
 13 period established for the open enrollment period es-
 14 tablished under section 1860D–2(b)(2), to each indi-
 15 vidual who is a policyholder or certificate holder of
 16 a medicare supplemental policy issued by that issuer
 17 that provides some coverage of expenses for prescrip-
 18 tion drugs (at the most recent available address of
 19 that individual) of—

20 “(A) the ability to enroll in a new medicare
 21 supplemental policy pursuant to paragraph (2);
 22 and

23 “(B) the fact that, so long as such indi-
 24 vidual retains coverage under such policy, the

1 *individual shall be ineligible for coverage of pre-*
 2 *scription drugs under part D.”.*

3 **(b) RULE OF CONSTRUCTION (1) IN GENERAL.—**

4 *Nothing in this Act shall be construed to require an issuer*
 5 *of a medicare supplemental policy under section 1882 of*
 6 *the Social Security Act (42 U.S.C. 1395rr) to participate*
 7 *as an eligible entity under part D of such Act, as added*
 8 *by section 101, as a condition for issuing such policy.*

9 **(2) PROHIBITION ON STATE REQUIREMENT.—A**

10 *State may not require an issuer of a medicare supple-*
 11 *mental policy under section 1882 of the Social Secu-*
 12 *rity Act (42 U.S.C. 1395rr) to participate as an eligi-*
 13 *ble entity under part D of such Act, as added by sec-*
 14 *tion 101, as a condition for issuing such policy.*

15 **SEC. 104. MEDICAID AND OTHER AMENDMENTS RELATED**
 16 **TO LOW-INCOME BENEFICIARIES.**

17 **(a) DETERMINATIONS OF ELIGIBILITY FOR LOW-IN-**
 18 **COME SUBSIDIES.—***Section 1902(a) (42 U.S.C. 1396a(a))*
 19 *is amended—*

20 *(1) by striking “and” at the end of paragraph*
 21 *(64);*

22 *(2) by striking the period at the end of para-*
 23 *graph (65) and inserting “; and”; and*

24 *(3) by inserting after paragraph (65) the fol-*
 25 *lowing new paragraph:*

1 “(66) provide for making eligibility determina-
2 tions under section 1935(a).”.

3 (b) *NEW SECTION.*—

4 (1) *IN GENERAL.*—*Title XIX (42 U.S.C. 1396 et*
5 *seq.) is amended—*

6 (A) *by redesignating section 1935 as section*
7 *1936; and*

8 (B) *by inserting after section 1934 the fol-*
9 *lowing new section:*

10 “*SPECIAL PROVISIONS RELATING TO MEDICARE*

11 *PRESCRIPTION DRUG BENEFIT*

12 “*SEC. 1935. (a) REQUIREMENT FOR MAKING ELIGI-*
13 *BILITY DETERMINATIONS FOR LOW-INCOME SUBSIDIES.*—

14 *As a condition of its State plan under this title under sec-*
15 *tion 1902(a)(66) and receipt of any Federal financial as-*
16 *sistance under section 1903(a), a State shall satisfy the fol-*
17 *lowing:*

18 “(1) *DETERMINATION OF ELIGIBILITY FOR TRAN-*

19 *SITIONAL PRESCRIPTION DRUG ASSISTANCE CARD*

20 *PROGRAM FOR ELIGIBLE LOW-INCOME BENE-*

21 *FICIARIES.*—*For purposes of section 1807A, submit to*

22 *the Secretary an eligibility plan under which the*

23 *State—*

24 “(A) *establishes eligibility standards con-*

25 *sistent with the provisions of that section;*

1 “(B) establishes procedures for providing
2 presumptive eligibility for eligible low-income
3 beneficiaries (as defined in section 1807A(i)(2))
4 under that section;

5 “(C) makes determinations of eligibility
6 and income for purposes of identifying eligible
7 low-income beneficiaries (as so defined) under
8 that section; and

9 “(D) communicates to the Secretary deter-
10 minations of eligibility or discontinuation of eli-
11 gibility under that section for purposes of noti-
12 fying prescription drug card sponsors under that
13 section of the identity of eligible medicare low-
14 income beneficiaries.

15 “(2) DETERMINATION OF ELIGIBILITY FOR PRE-
16 MIUM AND COST-SHARING SUBSIDIES UNDER PART D
17 OF TITLE XVIII FOR LOW-INCOME INDIVIDUALS.—Be-
18 ginning November 1, 2005, for purposes of section
19 1860D–19—

20 “(A) make determinations of eligibility for
21 premium and cost-sharing subsidies under and
22 in accordance with such section;

23 “(B) establish procedures for providing pre-
24 sumptive eligibility for individuals eligible for
25 subsidies under that section;

1 “(C) *inform the Administrator of the Center*
 2 *for Medicare Choices of such determinations in*
 3 *cases in which such eligibility is established; and*

4 “(D) *otherwise provide such Administrator*
 5 *with such information as may be required to*
 6 *carry out part D of title XVIII (including sec-*
 7 *tion 1860D–19).*

8 “(3) *AGREEMENT TO ESTABLISH INFORMATION*
 9 *AND ENROLLMENT SITES AT SOCIAL SECURITY FIELD*
 10 *OFFICES.—Enter into an agreement with the Com-*
 11 *missioner of Social Security to use all Social Security*
 12 *field offices located in the State as information and*
 13 *enrollment sites for making the eligibility determina-*
 14 *tions required under paragraphs (1) and (2).*

15 “(4) *SCREEN AND ENROLL INDIVIDUALS ELIGI-*
 16 *BLE FOR MEDICARE COST-SHARING.—As part of mak-*
 17 *ing an eligibility determination required under para-*
 18 *graph (1) or (2), screen an individual who applies for*
 19 *such a determination for eligibility for medical assist-*
 20 *ance for any medicare cost-sharing described in sec-*
 21 *tion 1905(p)(3) and, if the individual is eligible for*
 22 *any such medicare cost-sharing, enroll the individual*
 23 *under the State plan (or under a waiver of such*
 24 *plan).*

1 “(b) *FEDERAL SUBSIDY OF ADMINISTRATIVE*
2 *COSTS.*—

3 “(1) *ENHANCED MATCH FOR ELIGIBILITY DETER-*
4 *MINATIONS.*—*Subject to paragraphs (2) and (4), with*
5 *respect to calendar quarters beginning on or after*
6 *January 1, 2004, the amounts expended by a State*
7 *in carrying out subsection (a) are expenditures reim-*
8 *bursable under section 1903(a)(7) except that, in ap-*
9 *plying such section with respect to such expenditures*
10 *incurred for—*

11 “(A) *such calendar quarters occurring in*
12 *fiscal year 2004 or 2005, ‘75 percent’ shall be*
13 *substituted for ‘50 per centum’;*

14 “(B) *calendar quarters occurring in fiscal*
15 *year 2006, ‘70 percent’ shall be substituted for*
16 *‘50 per centum’;*

17 “(C) *calendar quarters occurring in fiscal*
18 *year 2007, ‘65 percent’ shall be substituted for*
19 *‘50 per centum’; and*

20 “(D) *calendar quarters occurring in fiscal*
21 *year 2008 or any fiscal year thereafter, ‘60 per-*
22 *cent’ shall be substituted for ‘50 per centum’.*

23 “(2) *100 PERCENT MATCH FOR ELIGIBILITY DE-*
24 *TERMINATIONS FOR SUBSIDY-ELIGIBLE INDIVID-*
25 *UALS.*—*In the case of amounts expended by a State*

1 *on or after November 1, 2005, to determine whether*
 2 *an individual is a subsidy-eligible individual for pur-*
 3 *poses of section 1860D–19, such expenditures shall be*
 4 *reimbursed under section 1903(a)(7) by substituting*
 5 *‘100 percent’ for ‘50 per centum’.*

6 “(3) *ENHANCED MATCH FOR UPDATES OR IM-*
 7 *PROVEMENTS TO ELIGIBILITY DETERMINATION SYS-*
 8 *TEMS.—With respect to calendar quarters occurring*
 9 *in fiscal year 2004, 2005, or 2006, the Secretary, in*
 10 *addition to amounts otherwise paid under section*
 11 *1903(a), shall pay to each State which has a plan ap-*
 12 *proved under this title, for each such quarter an*
 13 *amount equal to 90 percent of so much of the sums*
 14 *expended during such quarter as are attributable to*
 15 *the design, development, acquisition, or installation of*
 16 *improved eligibility determination systems (including*
 17 *hardware and software for such systems) in order to*
 18 *carry out the requirements of subsection (a) and sec-*
 19 *tion 1807A(h)(1). No payment shall be made to a*
 20 *State under the preceding sentence unless the State’s*
 21 *improved eligibility determination system—*

22 “(A) *satisfies such standards for improve-*
 23 *ment as the Secretary may establish; and*

24 “(B) *complies, and is compatible, with the*
 25 *standards established under part C of title XI*

1 *and any regulations promulgated under section*
 2 *264(c) of the Health Insurance Portability and*
 3 *Accountability Act of 1996 (42 U.S.C. 1320d–2*
 4 *note).*

5 “(4) *COORDINATION.—The State shall provide*
 6 *the Secretary with such information as may be nec-*
 7 *essary to properly allocate expenditures described in*
 8 *paragraph (1), (2), or (3) that may otherwise be*
 9 *made for similar eligibility determinations or expend-*
 10 *itures.*

11 “(c) *FEDERAL PAYMENT OF MEDICARE PART B PRE-*
 12 *MIUM FOR STATES PROVIDING PRESCRIPTION DRUG COV-*
 13 *ERAGE FOR DUAL ELIGIBLE INDIVIDUALS.—*

14 “(1) *IN GENERAL.—Subject to paragraph (4)*
 15 *and notwithstanding section 1905(b), in the case of a*
 16 *State that provides medical assistance for covered*
 17 *drugs (as such term is defined in section*
 18 *1860D(a)(2)) to dual eligible individuals under this*
 19 *title that satisfies the minimum standards described*
 20 *in paragraph (2), the Federal medical assistance per-*
 21 *centage shall be 100 percent for medicare cost-sharing*
 22 *described in section 1905(p)(3)(A)(ii) (relating to pre-*
 23 *miums under section 1839) for individuals—*

24 “(A) *who are dual eligible individuals or*
 25 *qualified medicare beneficiaries; and*

1 “(B) whose income is at least the income re-
 2 quired for an individual to be an eligible indi-
 3 vidual under section 1611 for purposes of the
 4 supplemental security income program (as deter-
 5 mined under section 1612), but does not exceed
 6 100 percent of the poverty line (as defined in sec-
 7 tion 2110(c)(5)) applicable to a family of the
 8 size involved.

9 “(2) *MINIMUM STANDARDS DESCRIBED.*—For
 10 purposes of paragraph (1), the minimum standards
 11 described in this paragraph are the following:

12 “(A) In providing medical assistance for
 13 dual eligible individuals for such covered drugs,
 14 the State satisfies the requirements of this title
 15 (including limitations on cost-sharing imposed
 16 under section 1916) applicable to the provision
 17 of medical assistance for prescribed drugs to dual
 18 eligible individuals.

19 “(B) In providing medical assistance for
 20 dual eligible individuals for such covered drugs,
 21 the State provides such individuals with bene-
 22 ficiary protections that the Secretary determines
 23 are equivalent to the beneficiary protections ap-
 24 plicable under section 1860D–5 to eligible enti-

1 *ties offering a Medicare Prescription Drug plan*
 2 *under part D of title XVIII.*

3 “(C) *In providing medical assistance for*
 4 *dual eligible individuals for such covered drugs,*
 5 *the State does not impose a limitation on the*
 6 *number of prescriptions an individual may have*
 7 *filled.*

8 “(3) *NONAPPLICATION.—Section 1927(d)(2)(E)*
 9 *shall not apply to a State for purposes of providing*
 10 *medical assistance for covered drugs (as such term is*
 11 *defined in section 1860D(a)(2)) to dual eligible indi-*
 12 *viduals that satisfies the minimum standards de-*
 13 *scribed in paragraph (2).*

14 “(4) *LIMITATION.—Paragraph (1) shall not*
 15 *apply to any State before January 1, 2006.*

16 “(d) *FEDERAL PAYMENT OF MEDICARE PART A COST-*
 17 *SHARING FOR CERTAIN STATES.—*

18 “(1) *IN GENERAL.—Subject to paragraph (2)*
 19 *and notwithstanding section 1905(b), in the case of a*
 20 *State that, as of the date of enactment of the Prescrip-*
 21 *tion Drug and Medicare Improvement Act of 2003,*
 22 *provides medical assistance for individuals described*
 23 *in section 1902(a)(10)(A)(ii)(X), the Federal medical*
 24 *assistance percentage shall be 100 percent for medi-*
 25 *care cost-sharing described in subparagraphs (B) and*

1 (C) of section 1905(p)(3) (relating to coinsurance and
 2 deductibles established under title XVIII) for the indi-
 3 viduals provided medical assistance under section
 4 1902(a)(10)(A)(ii)(X), but only—

5 “(A) with respect to such medicare cost-
 6 sharing that is incurred under part A of title
 7 XVIII; and

8 “(B) for so long as the State elects to pro-
 9 vide medical assistance under section
 10 1902(a)(10)(A)(ii)(X).

11 “(2) LIMITATION.—Paragraph (1) shall not
 12 apply to any State before January 1, 2006.

13 “(e) TREATMENT OF TERRITORIES.—

14 “(1) IN GENERAL.—In the case of a State, other
 15 than the 50 States and the District of Columbia—

16 “(A) the previous provisions of this section
 17 shall not apply to residents of such State; and

18 “(B) if the State establishes a plan de-
 19 scribed in paragraph (2), the amount otherwise
 20 determined under section 1108(f) (as increased
 21 under section 1108(g)) for the State shall be fur-
 22 ther increased by the amount specified in para-
 23 graph (3).

24 “(2) PLAN.—The plan described in this para-
 25 graph is a plan that—

1 “(A) provides medical assistance with re-
 2 spect to the provision of covered drugs (as de-
 3 fined in section 1860D(a)(2)) to individuals de-
 4 scribed in subparagraph (A), (B), (C), or (D) of
 5 section 1860D–19(a)(3); and

6 “(B) ensures that additional amounts re-
 7 ceived by the State that are attributable to the
 8 operation of this subsection are used only for
 9 such assistance.

10 “(3) INCREASED AMOUNT.—

11 “(A) IN GENERAL.—The amount specified
 12 in this paragraph for a State for a fiscal year
 13 is equal to the product of—

14 “(i) the aggregate amount specified in
 15 subparagraph (B); and

16 “(ii) the amount specified in section
 17 1108(g)(1) for that State, divided by the
 18 sum of the amounts specified in such section
 19 for all such States.

20 “(B) AGGREGATE AMOUNT.—The aggregate
 21 amount specified in this subparagraph for—

22 “(i) the last 3 quarters of fiscal year
 23 2006, is equal to \$37,500,000;

24 “(ii) fiscal year 2007, is equal to
 25 \$50,000,000; and

1 “(iii) any subsequent fiscal year, is
 2 equal to the aggregate amount specified in
 3 this subparagraph for the previous fiscal
 4 year increased by the annual percentage in-
 5 crease specified in section 1860D–6(c)(5) for
 6 the calendar year beginning in such fiscal
 7 year.

8 “(4) NONAPPLICATION.—Section 1927(d)(2)(E)
 9 shall not apply to a State described in paragraph (1)
 10 for purposes of providing medical assistance described
 11 in paragraph (2)(A).

12 “(5) REPORT.—The Secretary shall submit to
 13 Congress a report on the application of this subsection
 14 and may include in the report such recommendations
 15 as the Secretary deems appropriate.

16 “(f) DEFINITIONS.—For purposes of this section, the
 17 terms ‘qualified medicare beneficiary’, ‘subsidy-eligible in-
 18 dividual’, and ‘dual eligible individual’ have the meanings
 19 given such terms in subparagraphs (A), (D), and (E), re-
 20 spectively, of section 1860D–19(a)(4).”.

21 (2) CONFORMING AMENDMENTS.—

22 (A) Section 1905(b) (42 U.S.C. 1396d(b)) is
 23 amended by inserting “and subsections (c)(1)
 24 and (d)(1) of section 1935” after “1933(d)”.

1 (B) Section 1108(f) (42 U.S.C. 1308(f)) is
 2 amended by inserting “and section
 3 1935(e)(1)(B)” after “Subject to subsection (g)”.

4 (3) TRANSFER OF FEDERALLY ASSUMED POR-
 5 TIONS OF MEDICARE COST-SHARING.—

6 (A) TRANSFER OF ASSUMPTION OF PART B
 7 PREMIUM FOR STATES PROVIDING PRESCRIPTION
 8 DRUG COVERAGE FOR DUAL ELIGIBLE INDIVID-
 9 UALS TO THE FEDERAL SUPPLEMENTARY MED-
 10 ICAL INSURANCE TRUST FUND.—Section 1841(f)
 11 (42 U.S.C. 1395t(f)) is amended—

12 (i) by inserting “(1)” after “(f)”; and
 13 (ii) by adding at the end the following
 14 new paragraph:

15 “(2) There shall be transferred periodically (but not
 16 less often than once each fiscal year) to the Trust Fund from
 17 the Treasury amounts which the Secretary of Health and
 18 Human Services shall have certified are equivalent to the
 19 amounts determined under section 1935(c)(1) with respect
 20 to all States for a fiscal year.”.

21 (B) TRANSFER OF ASSUMPTION OF PART A
 22 COST-SHARING FOR CERTAIN STATES.—Section
 23 1817(g) (42 U.S.C. 1395i(g)) is amended—

24 (i) by inserting “(1)” after “(g)”; and

1 (ii) by adding at the end the following
2 new paragraph:

3 “(2) There shall be transferred periodically (but not
4 less often than once each fiscal year) to the Trust Fund from
5 the Treasury amounts which the Secretary of Health and
6 Human Services shall have certified are equivalent to the
7 amounts determined under section 1935(d)(1) with respect
8 to certain States for a fiscal year.”.

9 (4) AMENDMENT TO BEST PRICE.—Section
10 1927(c)(1)(C)(i) (42 U.S.C. 1396r–8(c)(1)(C)(i)), as
11 amended by section 111(b), is amended—

12 (A) by striking “and” at the end of sub-
13 clause (IV);

14 (B) by striking the period at the end of sub-
15 clause (V) and inserting “; and”; and

16 (C) by adding at the end the following new
17 subclause:

18 “(VI) any prices charged which
19 are negotiated under a Medicare Pre-
20 scription Drug plan under part D of
21 title XVIII with respect to covered
22 drugs, under a MedicareAdvantage
23 plan under part C of such title with
24 respect to such drugs, or under a quali-
25 fied retiree prescription drug plan (as

1 *defined in section 1860D–20(f)(1))*
 2 *with respect to such drugs, on behalf of*
 3 *eligible beneficiaries (as defined in sec-*
 4 *tion 1860D(a)(3)).”.*

5 (c) *EXTENSION OF MEDICARE COST-SHARING FOR*
 6 *PART B PREMIUM FOR QUALIFYING INDIVIDUALS*
 7 *THROUGH 2008.—*

8 (1) *IN GENERAL.—Section 1902(a)(10)(E)(iv)*
 9 *(42 U.S.C. 1396a(a)(10)(E)(iv)) is amended to read*
 10 *as follows:*

11 *“(iv) subject to sections 1933 and*
 12 *1905(p)(4), for making medical assistance avail-*
 13 *able (but only for premiums payable with respect*
 14 *to months during the period beginning with Jan-*
 15 *uary 1998, and ending with December 2008) for*
 16 *medicare cost-sharing described in section*
 17 *1905(p)(3)(A)(ii) for individuals who would be*
 18 *qualified medicare beneficiaries described in sec-*
 19 *tion 1905(p)(1) but for the fact that their income*
 20 *exceeds the income level established by the State*
 21 *under section 1905(p)(2) and is at least 120 per-*
 22 *cent, but less than 135 percent, of the official*
 23 *poverty line (referred to in such section) for a*
 24 *family of the size involved and who are not oth-*

1 *erwise eligible for medical assistance under the*
 2 *State plan;”.*

3 (2) *TOTAL AMOUNT AVAILABLE FOR ALLOCA-*
 4 *TION.—Section 1933(c) (42 U.S.C. 1396u–3(c)) is*
 5 *amended—*

6 (A) *in paragraph (1)—*

7 (i) *in subparagraph (D), by striking*
 8 *“and” at the end;*

9 (ii) *in subparagraph (E)—*

10 (I) *by striking “fiscal year 2002”*
 11 *and inserting “each of fiscal years*
 12 *2002 through 2008”; and*

13 (II) *by striking the period and in-*
 14 *serting “; and”; and*

15 (iii) *by adding at the end the following*
 16 *new subparagraph:*

17 *“(F) the first quarter of fiscal year 2009,*
 18 *\$100,000,000.”; and*

19 (B) *in paragraph (2)(A), by striking “the*
 20 *sum of” and all that follows through*
 21 *“1902(a)(10)(E)(iv)(II) in the State; to” and in-*
 22 *serting “twice the total number of individuals*
 23 *described in section 1902(a)(10)(E)(iv) in the*
 24 *State; to”.*

1 (d) *OUTREACH BY THE COMMISSIONER OF SOCIAL SE-*
 2 *CURITY.—Section 1144 (42 U.S.C. 1320b–14) is amended—*

3 (1) *in the section heading, by inserting “AND*
 4 *SUBSIDIES FOR LOW-INCOME INDIVIDUALS UNDER*
 5 *TITLE XVIII” after “COST-SHARING”;*

6 (2) *in subsection (a)—*

7 (A) *in paragraph (1)—*

8 (i) *in subparagraph (A), by inserting*
 9 *“for the transitional prescription drug as-*
 10 *sistance card program under section 1807A,*
 11 *or for premium and cost-sharing subsidies*
 12 *under section 1860D–19” before the semi-*
 13 *colon; and*

14 (ii) *in subparagraph (B), by inserting*
 15 *“, program, and subsidies” after “medical*
 16 *assistance”;* and

17 (B) *in paragraph (2)—*

18 (i) *in the matter preceding subpara-*
 19 *graph (A), by inserting “, the transitional*
 20 *prescription drug assistance card program*
 21 *under section 1807A, or premium and cost-*
 22 *sharing subsidies under section 1860D–19”*
 23 *after “assistance”;* and

24 (ii) *in subparagraph (A), by striking*
 25 *“such eligibility” and inserting “eligibility*

1 *for medicare cost-sharing under the med-*
 2 *icaid program”; and*

3 *(3) in subsection (b)—*

4 *(A) in paragraph (1)(A), by inserting “, for*
 5 *the transitional prescription drug assistance*
 6 *card program under section 1807A, or for pre-*
 7 *mium and cost-sharing subsidies for low-income*
 8 *individuals under section 1860D–19” after*
 9 *“1933”;*

10 *(B) in paragraph (2), by inserting “, pro-*
 11 *gram, and subsidies” after “medical assistance”;*
 12 *and*

13 *(C) by adding at the end the following:*

14 *“(3) AGREEMENTS TO ESTABLISH INFORMATION*
 15 *AND ENROLLMENT SITES AT SOCIAL SECURITY FIELD*
 16 *OFFICES.—*

17 *“(A) IN GENERAL.—The Commissioner shall*
 18 *enter into an agreement with each State oper-*
 19 *ating a State plan under title XIX (including*
 20 *under a waiver of such plan) to establish infor-*
 21 *mation and enrollment sites within all the So-*
 22 *cial Security field offices located in the State for*
 23 *purposes of—*

24 *“(i) the State determining the eligi-*
 25 *bility of individuals residing in the State*

1 *for medical assistance for payment of the*
 2 *cost of medicare cost-sharing under the med-*
 3 *icaid program pursuant to sections*
 4 *1902(a)(10)(E) and 1933, the transitional*
 5 *prescription drug assistance card program*
 6 *under section 1807A, or premium and cost-*
 7 *sharing subsidies under section 1860D–19;*
 8 *and*

9 “(ii) enrolling individuals who are de-
 10 *termined eligible for such medical assist-*
 11 *ance, program, or subsidies in the State*
 12 *plan (or waiver), the transitional prescrip-*
 13 *tion drug assistance card program under*
 14 *section 1807A, or the appropriate category*
 15 *for premium and cost-sharing subsidies*
 16 *under section 1860D–19.*

17 “(B) *AGREEMENT TERMS.*—*The Secretary*
 18 *and the Commissioner jointly shall develop terms*
 19 *for the State agreements required under subpara-*
 20 *graph (A) that shall specify the responsibilities*
 21 *of the State and the Commissioner in the estab-*
 22 *lishment and operation of such sites.*

23 “(C) *AUTHORIZATION OF APPROPRIA-*
 24 *TIONS.*—*There are authorized to be appropriated*

1 to the Commissioner, such sums as may be nec-
 2 essary to carry out this paragraph.”.

3 (e) *REPORT REGARDING VOLUNTARY ENROLLMENT OF*
 4 *DUAL ELIGIBLE INDIVIDUALS IN PART D.*—Not later than
 5 January 1, 2005, the Secretary shall submit a report to
 6 Congress that contains such recommendations for legisla-
 7 tion as the Secretary determines are necessary in order to
 8 establish a voluntary option for dual eligible individuals
 9 (as defined in 1860D–19(a)(4)(E) of the Social Security
 10 Act (as added by section 101)) to enroll under part D of
 11 title XVIII of such Act for prescription drug coverage.

12 **SEC. 105. EXPANSION OF MEMBERSHIP AND DUTIES OF**
 13 **MEDICARE PAYMENT ADVISORY COMMISSION**
 14 **(MEDPAC).**

15 (a) *EXPANSION OF MEMBERSHIP.*—

16 (1) *IN GENERAL.*—Section 1805(c) (42 U.S.C.
 17 1395b–6(c)) is amended—

18 (A) in paragraph (1), by striking “17” and
 19 inserting “19”; and

20 (B) in paragraph (2)(B), by inserting “ex-
 21 perts in the area of pharmacology and prescrip-
 22 tion drug benefit programs,” after “other health
 23 professionals,”.

24 (2) *INITIAL TERMS OF ADDITIONAL MEMBERS.*—

1 (A) *IN GENERAL.*—For purposes of stag-
 2 gering the initial terms of members of the Medi-
 3 care Payment Advisory Commission under sec-
 4 tion 1805(c)(3) of the Social Security Act (42
 5 U.S.C. 1395b–6(c)(3)), the initial terms of the 2
 6 additional members of the Commission provided
 7 for by the amendment under paragraph (1)(A)
 8 are as follows:

9 (i) One member shall be appointed for
 10 1 year.

11 (ii) One member shall be appointed for
 12 2 years.

13 (B) *COMMENCEMENT OF TERMS.*—Such
 14 terms shall begin on January 1, 2005.

15 (b) *EXPANSION OF DUTIES.*—Section 1805(b)(2) (42
 16 U.S.C. 1395b–6(b)(2)) is amended by adding at the end the
 17 following new subparagraph:

18 “(D) *VOLUNTARY PRESCRIPTION DRUG DE-*
 19 *LIVERY PROGRAM.*—Specifically, the Commission
 20 shall review, with respect to the voluntary pre-
 21 scription drug delivery program under part D,
 22 competition among eligible entities offering
 23 Medicare Prescription Drug plans and bene-
 24 ficiary access to such plans and covered drugs,
 25 particularly in rural areas. As part of such re-

1 *view, the Commission shall hold 3 field hearings*
 2 *in 2007.”.*

3 **SEC. 106. STUDY REGARDING VARIATIONS IN SPENDING**
 4 **AND DRUG UTILIZATION.**

5 *(a) STUDY.—The Secretary shall study on an ongoing*
 6 *basis variations in spending and drug utilization under*
 7 *part D of title XVIII of the Social Security Act for covered*
 8 *drugs to determine the impact of such variations on pre-*
 9 *miums imposed by eligible entities offering Medicare Pre-*
 10 *scription Drug plans under that part. In conducting such*
 11 *study, the Secretary shall examine the impact of geographic*
 12 *adjustments of the monthly national average premium*
 13 *under section 1860D–15 of such Act on—*

14 *(1) maximization of competition under part D of*
 15 *title XVIII of such Act; and*

16 *(2) the ability of eligible entities offering Medi-*
 17 *care Prescription Drug plans to contain costs for cov-*
 18 *ered drugs.*

19 *(b) REPORT.—Beginning with 2007, the Secretary*
 20 *shall submit annual reports to Congress on the study re-*
 21 *quired under subsection (a).*

22 **SEC. 107. LIMITATION ON PRESCRIPTION DRUG BENEFITS**
 23 **OF MEMBERS OF CONGRESS.**

24 *(a) LIMITATION ON BENEFITS.—Notwithstanding any*
 25 *other provision of law, during calendar year 2004, the actu-*

1 *arial value of the prescription drug benefit of any Member*
 2 *of Congress enrolled in a health benefits plan under chapter*
 3 *89 of title 5, United States Code, may not exceed the actu-*
 4 *arial value of any prescription drug benefit under title*
 5 *XVIII of the Social Security Act passed by the 1st session*
 6 *of the 108th Congress and enacted in law.*

7 (b) *REGULATIONS.—The Office of Personnel Manage-*
 8 *ment shall promulgate regulations to carry out this section.*

9 **SEC. 108. PROTECTING SENIORS WITH CANCER.**

10 *Any eligible beneficiary (as defined in section 1860D(3)*
 11 *of the Social Security Act) who is diagnosed with cancer*
 12 *shall be protected from high prescription drug costs in the*
 13 *following manner:*

14 (1) *SUBSIDY ELIGIBLE INDIVIDUALS WITH AN IN-*
 15 *COME BELOW 100 PERCENT OF THE FEDERAL POV-*
 16 *ERTY LINE.—If the individual is a qualified medicare*
 17 *beneficiary (as defined in section 1860D–19(a)(4) of*
 18 *such Act), such individual shall receive the full pre-*
 19 *mium subsidy and reduction of cost-sharing described*
 20 *in section 1860D–19(a)(1) of such Act, including the*
 21 *payment of—*

22 (A) *no deductible;*

23 (B) *no monthly beneficiary premium for at*
 24 *least one Medicare Prescription Drug plan avail-*

1 able in the area in which the individual resides;
2 and

3 (C) reduced cost-sharing described in sub-
4 paragraphs (C), (D), and (E) of section 1860D–
5 19(a)(1) of such Act.

6 (2) *SUBSIDY ELIGIBLE INDIVIDUALS WITH AN IN-*
7 *COME BETWEEN 100 AND 135 PERCENT OF THE FED-*
8 *ERAL POVERTY LINE.*—*If the individual is a specified*
9 *low income medicare beneficiary (as defined in para-*
10 *graph 1860D–19(4)(B) of such Act) or a qualifying*
11 *individual (as defined in paragraph 1860D–19(4)(C)*
12 *of such Act) who is diagnosed with cancer, such indi-*
13 *vidual shall receive the full premium subsidy and re-*
14 *duction of cost-sharing described in section 1860D–*
15 *19(a)(2) of such Act, including payment of—*

16 (A) no deductible;

17 (B) no monthly premium for any Medicare
18 Prescription Drug plan described paragraph (1)
19 or (2) of section 1860D–17(a) of such Act; and

20 (C) reduced cost-sharing described in sub-
21 paragraphs (C), (D), and (E) of section 1860D–
22 19(a)(2) of such Act.

23 (3) *SUBSIDY-ELIGIBLE INDIVIDUALS WITH IN-*
24 *COME BETWEEN 135 PERCENT AND 160 PERCENT OF*
25 *THE FEDERAL POVERTY LEVEL.*—*If the individual is*

1 *a subsidy-eligible individual (as defined in section*
 2 *1860D–19(a)(4)(D) of such Act) who is diagnosed*
 3 *with cancer, such individual shall receive sliding scale*
 4 *premium subsidy and reduction of cost-sharing for*
 5 *subsidy-eligible individuals, including payment of—*

6 *(A) for 2006, a deductible of only \$50;*

7 *(B) only a percentage of the monthly pre-*
 8 *mium (as described in section 1860D–*
 9 *19(a)(3)(A)(i)); and*

10 *(C) reduced cost-sharing described in*
 11 *clauses (iii), (iv), and (v) of section 1860D–*
 12 *19(a)(3)(A).*

13 *(4) ELIGIBLE BENEFICIARIES WITH INCOME*
 14 *ABOVE 160 PERCENT OF THE FEDERAL POVERTY*
 15 *LEVEL.—If an individual is an eligible beneficiary*
 16 *(as defined in section 1860D(3) of such Act), is not*
 17 *described in paragraphs (1) through (3), and is diag-*
 18 *nosed with cancer, such individual shall have access*
 19 *to qualified prescription drug coverage (as described*
 20 *in section 1860D–6(a)(1) of such Act), including pay-*
 21 *ment of—*

22 *(A) for 2006, a deductible of \$275;*

23 *(B) the limits on cost-sharing described sec-*
 24 *tion 1860D–6(c)(2) of such Act up to, for 2006,*
 25 *an initial coverage limit of \$4,500; and*

1 (C) for 2006, an annual out-of-pocket limit
 2 of \$3,700 with 10 percent cost-sharing after that
 3 limit is reached.

4 **SEC. 109. PROTECTING SENIORS WITH CARDIOVASCULAR**
 5 **DISEASE, CANCER, OR ALZHEIMER'S DISEASE.**

6 Any eligible beneficiary (as defined in section 1860D(3)
 7 of the Social Security Act) who is diagnosed with cardio-
 8 vascular disease, cancer, diabetes or Alzheimer's disease
 9 shall be protected from high prescription drug costs in the
 10 following manner:

11 (1) *SUBSIDY ELIGIBLE INDIVIDUALS WITH AN IN-*
 12 *COME BELOW 100 PERCENT OF THE FEDERAL POV-*
 13 *ERTY LINE.*—If the individual is a qualified medicare
 14 beneficiary (as defined in section 1860D–19(a)(4) of
 15 such Act), such individual shall receive the full pre-
 16 mium subsidy and reduction of cost-sharing described
 17 in section 1860D–19(a)(1) of such Act, including the
 18 payment of—

19 (A) no deductible;

20 (B) no monthly beneficiary premium for at
 21 least one Medicare Prescription Drug plan avail-
 22 able in the area in which the individual resides;
 23 and

1 (C) reduced cost-sharing described in sub-
 2 paragraphs (C), (D), and (E) of section 1860D–
 3 19(a)(1) of such Act.

4 (2) *SUBSIDY ELIGIBLE INDIVIDUALS WITH AN IN-*
 5 *COME BETWEEN 100 AND 135 PERCENT OF THE FED-*
 6 *ERAL POVERTY LINE.*—*If the individual is a specified*
 7 *low income medicare beneficiary (as defined in para-*
 8 *graph 1860D–19(4)(B) of such Act) or a qualifying*
 9 *individual (as defined in paragraph 1860D–19(4)(C)*
 10 *of such Act) who is diagnosed with cardiovascular*
 11 *disease, cancer, or Alzheimer’s disease, such indi-*
 12 *vidual shall receive the full premium subsidy and re-*
 13 *duction of cost-sharing described in section 1860D–*
 14 *19(a)(2) of such Act, including payment of—*

15 (A) no deductible;

16 (B) no monthly premium for any Medicare
 17 Prescription Drug plan described paragraph (1)
 18 or (2) of section 1860D–17(a) of such Act; and

19 (C) reduced cost-sharing described in sub-
 20 paragraphs (C), (D), and (E) of section 1860D–
 21 19(a)(2) of such Act.

22 (3) *SUBSIDY-ELIGIBLE INDIVIDUALS WITH IN-*
 23 *COME BETWEEN 135 PERCENT AND 160 PERCENT OF*
 24 *THE FEDERAL POVERTY LEVEL.*—*If the individual is*
 25 *a subsidy-eligible individual (as defined in section*

1860D–19(a)(4)(D) of such Act) who is diagnosed with cardiovascular disease, cancer, or Alzheimer’s disease, such individual shall receive sliding scale premium subsidy and reduction of cost-sharing for subsidy-eligible individuals, including payment of—

(A) for 2006, a deductible of only \$50;

(B) only a percentage of the monthly premium (as described in section 1860D–19(a)(3)(A)(i)); and

(C) reduced cost-sharing described in clauses (iii), (iv), and (v) of section 1860D–19(a)(3)(A).

(4) *ELIGIBLE BENEFICIARIES WITH INCOME ABOVE 160 PERCENT OF THE FEDERAL POVERTY LEVEL.*—If an individual is an eligible beneficiary (as defined in section 1860D(3) of such Act), is not described in paragraphs (1) through (3), and is diagnosed with cardiovascular disease, cancer, or Alzheimer’s disease, such individual shall have access to qualified prescription drug coverage (as described in section 1860D–6(a)(1) of such Act), including payment of—

(A) for 2006, a deductible of \$275;

1 (B) the limits on cost-sharing described sec-
 2 tion 1860D–6(c)(2) of such Act up to, for 2006,
 3 an initial coverage limit of \$4,500; and

4 (C) for 2006, an annual out-of-pocket limit
 5 of \$3,700 with 10 percent cost-sharing after that
 6 limit is reached.

7 **SEC. 110. REVIEW AND REPORT ON CURRENT STANDARDS**
 8 **OF PRACTICE FOR PHARMACY SERVICES PRO-**
 9 **VIDED TO PATIENTS IN NURSING FACILITIES.**

10 (a) *REVIEW.*—

11 (1) *IN GENERAL.*—The Secretary shall conduct a
 12 thorough review of the current standards of practice
 13 for pharmacy services provided to patients in nursing
 14 facilities.

15 (2) *SPECIFIC MATTERS REVIEWED.*—In con-
 16 ducting the review under paragraph (1), the Sec-
 17 retary shall—

18 (A) assess the current standards of practice,
 19 clinical services, and other service requirements
 20 generally used for pharmacy services in long-
 21 term care settings; and

22 (B) evaluate the impact of those standards
 23 with respect to patient safety, reduction of medi-
 24 cation errors and quality of care.

25 (b) *REPORT.*—

1 (1) *IN GENERAL.*—Not later than the date that
 2 is 18 months after the date of enactment of this Act,
 3 the Secretary shall submit a report to Congress on the
 4 study conducted under subsection (a)(1), together with
 5 any recommendations for legislation that the Admin-
 6 istrator determines to be appropriate as a result of
 7 such study.

8 (2) *CONTENTS.*—The report submitted under
 9 paragraph (1) shall contain—

10 (A) a detailed description of the plans of the
 11 Secretary to implement the provisions of this Act
 12 in a manner consistent with applicable State
 13 and Federal laws designed to protect the safety
 14 and quality of care of nursing facility patients;
 15 and

16 (B) recommendations regarding necessary
 17 actions and appropriate reimbursement to en-
 18 sure the provision of prescription drugs to medi-
 19 care beneficiaries residing in nursing facilities
 20 in a manner consistent with existing patient
 21 safety and quality of care standards under ap-
 22 plicable State and Federal laws.

23 **SEC. 110A. MEDICATION THERAPY MANAGEMENT ASSESS-**
 24 **MENT PROGRAM.**

25 (a) *ESTABLISHMENT.*—

1 (1) *IN GENERAL.*—*The Secretary shall establish*
2 *an assessment program to contract with qualified*
3 *pharmacists to provide medication therapy manage-*
4 *ment services to eligible beneficiaries who receive care*
5 *under the original medicare fee-for-service program*
6 *under parts A and B of title XVIII of the Social Se-*
7 *curity Act to eligible beneficiaries.*

8 (2) *SITES.*—*The Secretary shall designate 6 geo-*
9 *graphic areas, each containing not less than 3 sites,*
10 *at which to conduct the assessment program under*
11 *this section. At least 2 geographic areas designated*
12 *under this paragraph shall be located in rural areas.*

13 (3) *DURATION.*—*The Secretary shall conduct the*
14 *assessment program under this section for a 1-year*
15 *period.*

16 (4) *IMPLEMENTATION.*—*The Secretary shall im-*
17 *plement the program not later than January 1, 2005,*
18 *but may not implement the assessment program be-*
19 *fore October 1, 2004.*

20 (b) *PARTICIPANTS.*—*Any eligible beneficiary who re-*
21 *sides in an area designated by the Secretary as an assess-*
22 *ment site under subsection (a)(2) may participate in the*
23 *assessment program under this section if such beneficiary*
24 *identifies a qualified pharmacist who agrees to furnish*

1 medication therapy management services to the eligible ben-
 2 eficiary under the assessment program.

3 (c) *CONTRACTS WITH QUALIFIED PHARMACISTS.*—

4 (1) *IN GENERAL.*—*The Secretary shall enter into*
 5 *a contract with qualified pharmacists to provide*
 6 *medication therapy management services to eligible*
 7 *beneficiaries residing in the area served by the quali-*
 8 *fied pharmacist.*

9 (2) *NUMBER OF QUALIFIED PHARMACISTS.*—*The*
 10 *Secretary may contract with more than 1 qualified*
 11 *pharmacist at each site.*

12 (d) *PAYMENT TO QUALIFIED PHARMACISTS.*—

13 (1) *IN GENERAL.*—*Under an contract entered*
 14 *into under subsection (c), the Secretary shall pay*
 15 *qualified pharmacists a fee for providing medication*
 16 *therapy management services.*

17 (2) *ASSESSMENT OF PAYMENT METHODOLO-*
 18 *GIES.*—*The Secretary shall, in consultation with na-*
 19 *tional pharmacist and pharmacy associations, design*
 20 *the fee paid under paragraph (1) to test various pay-*
 21 *ment methodologies applicable with respect to medica-*
 22 *tion therapy management services, including a pay-*
 23 *ment methodology that applies a relative value scale*
 24 *and fee-schedule with respect to such services that take*
 25 *into account the differences in—*

1 (A) the time required to perform the dif-
 2 ferent types of medication therapy management
 3 services;

4 (B) the level of risk associated with the use
 5 of particular outpatient prescription drugs or
 6 groups of drugs; and

7 (C) the health status of individuals to whom
 8 such services are provided.

9 (e) *FUNDING.*—

10 (1) *IN GENERAL.*—Subject to paragraph (2), the
 11 Secretary shall provide for the transfer from the Fed-
 12 eral Supplementary Insurance Trust Fund established
 13 under section 1841 of the Social Security Act (42
 14 U.S.C. 1395t) of such funds as are necessary for the
 15 costs of carrying out the assessment program under
 16 this section.

17 (2) *BUDGET NEUTRALITY.*—In conducting the
 18 assessment program under this section, the Secretary
 19 shall ensure that the aggregate payments made by the
 20 Secretary do not exceed the amount which the Sec-
 21 retary would have paid if the assessment program
 22 under this section was not implemented.

23 (f) *WAIVER AUTHORITY.*—The Secretary may waive
 24 such requirements of titles XI and XVIII of the Social Secu-
 25 rity Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be

1 *necessary for the purpose of carrying out the assessment*
2 *program under this section.*

3 *(g) AVAILABILITY OF DATA.—During the period in*
4 *which the assessment program is conducted, the Secretary*
5 *annually shall make available data regarding—*

6 *(1) the geographic areas and sites designated*
7 *under subsection (a)(2);*

8 *(2) the number of eligible beneficiaries partici-*
9 *pating in the program under subsection (b) and the*
10 *level and types medication therapy management serv-*
11 *ices used by such beneficiaries;*

12 *(3) the number of qualified pharmacists with*
13 *contracts under subsection (c), the location of such*
14 *pharmacists, and the number of eligible beneficiaries*
15 *served by such pharmacists; and*

16 *(4) the types of payment methodologies being*
17 *tested under subsection (d)(2).*

18 *(h) REPORT.—*

19 *(1) IN GENERAL.—Not later than 6 months after*
20 *the completion of the assessment program under this*
21 *section, the Secretary shall submit to Congress a final*
22 *report summarizing the final outcome of the program*
23 *and evaluating the results of the program, together*
24 *with recommendations for such legislation and ad-*

1 *ministrative action as the Secretary determines to be*
 2 *appropriate.*

3 (2) *ASSESSMENT OF PAYMENT METHODOLO-*
 4 *GIES.—The final report submitted under paragraph*
 5 *(1) shall include an assessment of the feasibility and*
 6 *appropriateness of the various payment methodologies*
 7 *tested under subsection (d)(2).*

8 (i) *DEFINITIONS.—In this section:*

9 (1) *MEDICATION THERAPY MANAGEMENT SERV-*
 10 *ICES.—The term “medication therapy management*
 11 *services” means services or programs furnished by a*
 12 *qualified pharmacist to an eligible beneficiary, indi-*
 13 *vidually or on behalf of a pharmacy provider, which*
 14 *are designed—*

15 (A) *to ensure that medications are used ap-*
 16 *propriately by such individual;*

17 (B) *to enhance the individual’s under-*
 18 *standing of the appropriate use of medications;*

19 (C) *to increase the individual’s compliance*
 20 *with prescription medication regimens;*

21 (D) *to reduce the risk of potential adverse*
 22 *events associated with medications; and*

23 (E) *to reduce the need for other costly med-*
 24 *ical services through better management of medi-*
 25 *cation therapy.*

1 (2) *ELIGIBLE BENEFICIARY*.—The term “eligible
2 beneficiary” means an individual who is—

3 (A) entitled to (or enrolled for) benefits
4 under part A and enrolled for benefits under
5 part B of the Social Security Act (42 U.S.C.
6 1395c et seq.; 1395j et seq.);

7 (B) not enrolled with a Medicare+Choice
8 plan or a MedicareAdvantage plan under part
9 C; and

10 (C) receiving, in accordance with State law
11 or regulation, medication for—

12 (i) the treatment of asthma, diabetes,
13 or chronic cardiovascular disease, including
14 an individual on anticoagulation or lipid
15 reducing medications; or

16 (ii) such other chronic diseases as the
17 Secretary may specify.

18 (3) *QUALIFIED PHARMACIST*.—The term “quali-
19 fied pharmacist” means an individual who is a li-
20 censed pharmacist in good standing with the State
21 Board of Pharmacy.

1 ***Subtitle B—Medicare Prescription***
 2 ***Drug Discount Card and Transi-***
 3 ***tional Assistance for Low-In-***
 4 ***come Beneficiaries***

5 ***SEC. 111. MEDICARE PRESCRIPTION DRUG DISCOUNT CARD***
 6 ***AND TRANSITIONAL ASSISTANCE FOR LOW-***
 7 ***INCOME BENEFICIARIES.***

8 *(a) IN GENERAL.—Title XVIII is amended by insert-*
 9 *ing after section 1806 the following new sections:*

10 *“MEDICARE PRESCRIPTION DRUG DISCOUNT CARD*
 11 *ENDORSEMENT PROGRAM*

12 *“SEC. 1807. (a) ESTABLISHMENT.—There is estab-*
 13 *lished a medicare prescription drug discount card endorse-*
 14 *ment program under which the Secretary shall—*

15 *“(1) endorse prescription drug discount card*
 16 *programs offered by prescription drug card sponsors*
 17 *that meet the requirements of this section; and*

18 *“(2) make available to eligible beneficiaries in-*
 19 *formation regarding such endorsed programs.*

20 *“(b) ELIGIBILITY, ELECTION OF PROGRAM, AND EN-*
 21 *ROLLMENT FEES.—*

22 *“(1) ELIGIBILITY AND ELECTION OF PROGRAM.—*

23 *“(A) IN GENERAL.—Subject to subpara-*
 24 *graph (B), the Secretary shall establish*
 25 *procedures—*

1 “(i) for identifying eligible bene-
2 ficiaries; and

3 “(ii) under which such beneficiaries
4 may make an election to enroll in any pre-
5 scription drug discount card program en-
6 dorsed under this section and disenroll from
7 such a program.

8 “(B) *LIMITATION.*—An eligible beneficiary
9 may not be enrolled in more than 1 prescription
10 drug discount card program at any time.

11 “(2) *ENROLLMENT FEES.*—

12 “(A) *IN GENERAL.*—A prescription drug
13 card sponsor may charge an annual enrollment
14 fee to each eligible beneficiary enrolled in a pre-
15 scription drug discount card program offered by
16 such sponsor.

17 “(B) *AMOUNT.*—No enrollment fee charged
18 under subparagraph (A) may exceed \$25.

19 “(C) *UNIFORM ENROLLMENT FEE.*—A pre-
20 scription drug card sponsor shall ensure that the
21 enrollment fee for a prescription drug discount
22 card program endorsed under this section is the
23 same for all eligible medicare beneficiaries en-
24 rolled in the program.

1 “(D) *COLLECTION.*—*Any enrollment fee*
 2 *shall be collected by the prescription drug card*
 3 *sponsor.*

4 “(c) *PROVIDING INFORMATION TO ELIGIBLE BENE-*
 5 *FICIARIES.*—

6 “(1) *PROMOTION OF INFORMED CHOICE.*—

7 “(A) *BY THE SECRETARY.*—*In order to pro-*
 8 *mote informed choice among endorsed prescrip-*
 9 *tion drug discount card programs, the Secretary*
 10 *shall provide for the dissemination of informa-*
 11 *tion which compares the costs and benefits of*
 12 *such programs. Such dissemination shall be co-*
 13 *ordinated with the dissemination of educational*
 14 *information on other medicare options.*

15 “(B) *BY PRESCRIPTION DRUG CARD SPON-*
 16 *SORS.*—*Each prescription drug card sponsor*
 17 *shall make available to each eligible beneficiary*
 18 *(through the Internet and otherwise)*
 19 *information—*

20 “(i) *that the Secretary identifies as*
 21 *being necessary to promote informed choice*
 22 *among endorsed prescription drug discount*
 23 *card programs by eligible beneficiaries, in-*
 24 *cluding information on enrollment fees, ne-*
 25 *gotiated prices for prescription drugs*

1 *charged to beneficiaries, and services relat-*
 2 *ing to prescription drugs offered under the*
 3 *program;*

4 “(ii) *on how any formulary used by*
 5 *such sponsor functions.*

6 “(2) *USE OF MEDICARE TOLL-FREE NUMBER.—*
 7 *The Secretary shall provide through the 1–800–*
 8 *MEDICARE toll free telephone number for the receipt*
 9 *and response to inquiries and complaints concerning*
 10 *the medicare prescription drug discount card endorse-*
 11 *ment program established under this section and pre-*
 12 *scription drug discount card programs endorsed*
 13 *under such program.*

14 “(d) *BENEFICIARY PROTECTIONS.—*

15 “(1) *IN GENERAL.—Each prescription drug dis-*
 16 *count card program endorsed under this section shall*
 17 *meet such requirements as the Secretary identifies to*
 18 *protect and promote the interest of eligible bene-*
 19 *ficiaries, including requirements that—*

20 “(A) *relate to appeals by eligible bene-*
 21 *ficiaries and marketing practices; and*

22 “(B) *ensure that beneficiaries are not*
 23 *charged more than the lower of the negotiated re-*
 24 *tail price or the usual and customary price.*

1 “(2) *ENSURING PHARMACY ACCESS.*—Each pre-
2 scription drug card sponsor offering a prescription
3 drug discount card program endorsed under this sec-
4 tion shall secure the participation in its network of
5 a sufficient number of pharmacies that dispense
6 (other than by mail order) drugs directly to patients
7 to ensure convenient access (as determined by the Sec-
8 retary and including adequate emergency access) for
9 enrolled beneficiaries. Such standards shall take into
10 account reasonable distances to pharmacy services in
11 urban and rural areas and access to pharmacy serv-
12 ices of the Indian Health Service and Indian tribes
13 and tribal organizations.

14 “(3) *QUALITY ASSURANCE.*—Each prescription
15 drug card sponsor offering a prescription drug dis-
16 count card program endorsed under this section shall
17 have in place adequate procedures for assuring that
18 quality service is provided to eligible beneficiaries en-
19 rolled in a prescription drug discount card program
20 offered by such sponsor.

21 “(4) *CONFIDENTIALITY OF ENROLLEE*
22 *RECORDS.*—Insofar as a prescription drug card spon-
23 sor maintains individually identifiable medical
24 records or other health information regarding eligible
25 beneficiaries enrolled in a prescription drug discount

1 *card program endorsed under this section, the pre-*
 2 *scription drug card sponsor shall have in place proce-*
 3 *dures to safeguard the privacy of any individually*
 4 *identifiable beneficiary information in a manner that*
 5 *the Secretary determines is consistent with the Fed-*
 6 *eral regulations (concerning the privacy of individ-*
 7 *ually identifiable health information) promulgated*
 8 *under section 264(c) of the Health Insurance Port-*
 9 *ability and Accountability Act of 1996.*

10 “(5) *NO OTHER FEES.*—A prescription drug
 11 *card sponsor may not charge any fee to an eligible*
 12 *beneficiary under a prescription drug discount card*
 13 *program endorsed under this section other than an*
 14 *enrollment fee charged under subsection (b)(2)(A).*

15 “(6) *PRICES.*—

16 “(A) *AVOIDANCE OF HIGH PRICED*
 17 *DRUGS.*—A prescription drug card sponsor may
 18 *not recommend switching an eligible beneficiary*
 19 *to a drug with a higher negotiated price absent*
 20 *a recommendation by a licensed health profes-*
 21 *sional that there is a clinical indication with re-*
 22 *spect to the patient for such a switch.*

23 “(B) *PRICE STABILITY.*—Negotiated prices
 24 *charged for prescription drugs covered under a*
 25 *prescription drug discount card program en-*

1 *dorsed under this section may not change more*
 2 *frequently than once every 60 days.*

3 “(e) *PRESCRIPTION DRUG BENEFITS.*—

4 “(1) *IN GENERAL.*—Each prescription drug card
 5 *sponsor may only provide benefits that relate to pre-*
 6 *scription drugs (as defined in subsection (i)(2)) under*
 7 *a prescription drug discount card program endorsed*
 8 *under this section.*

9 “(2) *SAVINGS TO ELIGIBLE BENEFICIARIES.*—

10 “(A) *IN GENERAL.*—Subject to subpara-
 11 *graph (D), each prescription drug card sponsor*
 12 *shall provide eligible beneficiaries who enroll in*
 13 *a prescription drug discount card program of-*
 14 *fered by such sponsor that is endorsed under this*
 15 *section with access to negotiated prices used by*
 16 *the sponsor with respect to prescription drugs*
 17 *dispensed to eligible beneficiaries.*

18 “(B) *INAPPLICABILITY OF MEDICAID BEST*
 19 *PRICE RULES.*—The requirements of section 1927
 20 *relating to manufacturer best price shall not*
 21 *apply to the negotiated prices for prescription*
 22 *drugs made available under a prescription drug*
 23 *discount card program endorsed under this sec-*
 24 *tion.*

1 “(C) *GUARANTEED ACCESS TO NEGOTIATED*
 2 *PRICES.—The Secretary, in consultation with the*
 3 *Inspector General of the Department of Health*
 4 *and Human Services, shall establish procedures*
 5 *to ensure that eligible beneficiaries have access to*
 6 *the negotiated prices for prescription drugs pro-*
 7 *vided under subparagraph (A).*

8 “(D) *APPLICATION OF FORMULARY RE-*
 9 *STRICTIONS.—A drug prescribed for an eligible*
 10 *beneficiary that would otherwise be a covered*
 11 *drug under this section shall not be so considered*
 12 *under a prescription drug discount card pro-*
 13 *gram if the program excludes the drug under a*
 14 *formulary.*

15 “(3) *BENEFICIARY SERVICES.—Each prescrip-*
 16 *tion drug discount card program endorsed under this*
 17 *section shall provide pharmaceutical support services,*
 18 *such as education, counseling, and services to prevent*
 19 *adverse drug interactions.*

20 “(4) *DISCOUNT CARDS.—Each prescription drug*
 21 *card sponsor shall issue a card to eligible beneficiaries*
 22 *enrolled in a prescription drug discount card pro-*
 23 *gram offered by such sponsor that the beneficiary may*
 24 *use to obtain benefits under the program.*

1 “(f) *SUBMISSION OF APPLICATIONS FOR ENDORSE-*
 2 *MENT AND APPROVAL.*—

3 “(1) *SUBMISSION OF APPLICATIONS FOR EN-*
 4 *DORSEMENT.*—*Each prescription drug card sponsor*
 5 *that seeks endorsement of a prescription drug dis-*
 6 *count card program under this section shall submit to*
 7 *the Secretary, at such time and in such manner as*
 8 *the Secretary may specify, such information as the*
 9 *Secretary may require.*

10 “(2) *APPROVAL.*—*The Secretary shall review the*
 11 *information submitted under paragraph (1) and shall*
 12 *determine whether to endorse the prescription drug*
 13 *discount card program to which such information re-*
 14 *lates. The Secretary may not approve a program un-*
 15 *less the program and prescription drug card sponsor*
 16 *offering the program comply with the requirements*
 17 *under this section.*

18 “(g) *REQUIREMENTS ON DEVELOPMENT AND APPLICA-*
 19 *TION OF FORMULARIES.*—*If a prescription drug card spon-*
 20 *sor offering a prescription drug discount card program uses*
 21 *a formulary, the following requirements must be met:*

22 “(1) *PHARMACY AND THERAPEUTIC (P&T) COM-*
 23 *MITTEE.*—

1 “(A) *IN GENERAL.*—*The eligible entity must*
 2 *establish a pharmacy and therapeutic committee*
 3 *that develops and reviews the formulary.*

4 “(B) *COMPOSITION.*—*A pharmacy and*
 5 *therapeutic committee shall include at least 1*
 6 *academic expert, at least 1 practicing physician,*
 7 *and at least 1 practicing pharmacist, all of*
 8 *whom have expertise in the care of elderly or dis-*
 9 *abled persons, and a majority of the members of*
 10 *such committee shall consist of individuals who*
 11 *are a practicing physician or a practicing phar-*
 12 *macist (or both).*

13 “(2) *FORMULARY DEVELOPMENT.*—*In developing*
 14 *and reviewing the formulary, the committee shall base*
 15 *clinical decisions on the strength of scientific evidence*
 16 *and standards of practice, including assessing peer-*
 17 *reviewed medical literature, such as randomized clin-*
 18 *ical trials, pharmacoeconomic studies, outcomes re-*
 19 *search data, and such other information as the com-*
 20 *mittee determines to be appropriate.*

21 “(3) *INCLUSION OF DRUGS IN ALL THERAPEUTIC*
 22 *CATEGORIES AND CLASSES.*—

23 “(A) *IN GENERAL.*—*The formulary must in-*
 24 *clude drugs within each therapeutic category and*
 25 *class of covered outpatient drugs (as defined by*

1 *the Secretary), although not necessarily for all*
 2 *drugs within such categories and classes.*

3 *“(B) REQUIREMENT.—In defining thera-*
 4 *peutic categories and classes of covered out-*
 5 *patient drugs pursuant to subparagraph (A), the*
 6 *Secretary shall use the compendia referred to sec-*
 7 *tion 1927(g)(1)(B)(i) or other recognized sources*
 8 *for categorizing drug therapeutic categories and*
 9 *classes.*

10 *“(4) PROVIDER EDUCATION.—The committee*
 11 *shall establish policies and procedures to educate and*
 12 *inform health care providers concerning the for-*
 13 *mulary.*

14 *“(5) NOTICE BEFORE REMOVING DRUGS FROM*
 15 *FORMULARY.—Any removal of a drug from a for-*
 16 *mulary shall take effect only after appropriate notice*
 17 *is made available to beneficiaries and pharmacies.*

18 *“(h) FRAUD AND ABUSE PREVENTION.—*

19 *“(1) IN GENERAL.—The Secretary shall provide*
 20 *appropriate oversight to ensure compliance of en-*
 21 *dorsed programs with the requirements of this section,*
 22 *including verification of the negotiated prices and*
 23 *services provided.*

24 *“(2) DISQUALIFICATION FOR ABUSIVE PRAC-*
 25 *TICES.—The Secretary may implement intermediate*

1 *sanctions and may revoke the endorsement of a pro-*
 2 *gram that the Secretary determines no longer meets*
 3 *the requirements of this section or that has engaged*
 4 *in false or misleading marketing practices.*

5 *“(3) AUTHORITY WITH RESPECT TO CIVIL MONEY*
 6 *PENALTIES.—The Secretary may impose a civil*
 7 *money penalty in an amount not to exceed \$10,000*
 8 *for any violation of this section. The provisions of sec-*
 9 *tion 1128A (other than subsections (a) and (b)) shall*
 10 *apply to a civil money penalty under the previous*
 11 *sentence in the same manner as such provisions apply*
 12 *to a penalty or proceeding under section 1128A(a).*

13 *“(4) REPORTING TO SECRETARY.—Each pre-*
 14 *scription drug card sponsor offering a prescription*
 15 *drug discount card program endorsed under this sec-*
 16 *tion shall report information relating to program per-*
 17 *formance, use of prescription drugs by eligible bene-*
 18 *ficiaries enrolled in the program, financial informa-*
 19 *tion of the sponsor, and such other information as the*
 20 *Secretary may specify. The Secretary may not dis-*
 21 *close any proprietary data reported under this para-*
 22 *graph.*

23 *“(5) DRUG UTILIZATION REVIEW.—The Sec-*
 24 *retary may use claims data from parts A and B for*

1 *purposes of conducting a drug utilization review pro-*
 2 *gram.*

3 “(i) *DEFINITIONS.—In this section:*

4 “(1) *ELIGIBLE BENEFICIARY.—*

5 “(A) *IN GENERAL.—The term ‘eligible bene-*
 6 *ficiary’ means an individual who—*

7 “(i) *is entitled to, or enrolled for, bene-*
 8 *fits under part A and enrolled under part*
 9 *B; and*

10 “(ii) *is not a dual eligible individual*
 11 *(as defined in subparagraph (B)).*

12 “(B) *DUAL ELIGIBLE INDIVIDUAL.—*

13 “(i) *IN GENERAL.—The term ‘dual eli-*
 14 *gible individual’ means an individual who*
 15 *is—*

16 “(I) *enrolled under title XIX or*
 17 *under a waiver under section 1115 of*
 18 *the requirements of such title for med-*
 19 *ical assistance that is not less than the*
 20 *medical assistance provided to an indi-*
 21 *vidual described in section*
 22 *1902(a)(10)(A)(i) and includes covered*
 23 *outpatient drugs (as such term is de-*
 24 *finied for purposes of section 1927); and*

1 “(II) entitled to benefits under
2 part A and enrolled under part B.

3 “(ii) INCLUSION OF MEDICALLY
4 NEEDY.—Such term includes an individual
5 described in section 1902(a)(10)(C).

6 “(2) PRESCRIPTION DRUG.—

7 “(A) IN GENERAL.—Except as provided in
8 subparagraph (B), the term ‘prescription drug’
9 means—

10 “(i) a drug that may be dispensed only
11 upon a prescription and that is described in
12 clause (i) or (ii) of subparagraph (A) of sec-
13 tion 1927(k)(2); or

14 “(ii) a biological product or insulin
15 described in subparagraph (B) or (C) of
16 such section (including syringes, and nec-
17 essary medical supplies associated with the
18 administration of insulin, as defined by the
19 Secretary),

20 and such term includes a vaccine licensed under
21 section 351 of the Public Health Service Act and
22 any use of a covered outpatient drug for a medi-
23 cally accepted indication (as defined in section
24 1927(k)(6)).

1 “(B) *EXCLUSIONS.*—The term ‘prescription
2 *drug*’ does not include drugs or classes of drugs,
3 *or their medical uses, which may be excluded*
4 *from coverage or otherwise restricted under sec-*
5 *tion 1927(d)(2), other than subparagraph (E)*
6 *thereof (relating to smoking cessation agents), or*
7 *under section 1927(d)(3).*

8 “(3) *NEGOTIATED PRICE.*—The term ‘negotiated
9 *price*’ includes all discounts, direct or indirect sub-
10 *sidies, rebates, price concessions, and direct or indi-*
11 *rect remunerations.*

12 “(4) *PRESCRIPTION DRUG CARD SPONSOR.*—The
13 term ‘prescription drug card sponsor’ means any en-
14 tity with demonstrated experience and expertise in
15 operating a prescription drug discount card program,
16 an insurance program that provides coverage for pre-
17 scription drugs, or a similar program that the Sec-
18 retary determines to be appropriate to provide eligible
19 beneficiaries with the benefits under a prescription
20 drug discount card program endorsed by the Sec-
21 retary under this section, including—

22 “(A) a pharmaceutical benefit management
23 company;

24 “(B) a wholesale or retail pharmacist deliv-
25 ery system;

1 “(C) *an insurer (including an insurer that*
 2 *offers medicare supplemental policies under sec-*
 3 *tion 1882);*

4 “(D) *any other entity; or*

5 “(E) *any combination of the entities de-*
 6 *scribed in subparagraphs (A) through (D).*

7 “TRANSITIONAL PRESCRIPTION DRUG ASSISTANCE CARD
 8 PROGRAM FOR ELIGIBLE LOW-INCOME BENEFICIARIES

9 “SEC. 1807A. (a) *ESTABLISHMENT.*—

10 “(1) *IN GENERAL.*—*There is established a pro-*
 11 *gram under which the Secretary shall award con-*
 12 *tracts to prescription drug card sponsors offering a*
 13 *prescription drug discount card that has been en-*
 14 *dorsed by the Secretary under section 1807 under*
 15 *which such sponsors shall offer a prescription drug*
 16 *assistance card program to eligible low-income bene-*
 17 *ficiaries in accordance with the requirements of this*
 18 *section.*

19 “(2) *APPLICATION OF DISCOUNT CARD PROVI-*
 20 *SIONS.*—*Except as otherwise provided in this section,*
 21 *the provisions of section 1807 shall apply to the pro-*
 22 *gram established under this section.*

23 “(b) *ELIGIBILITY, ELECTION OF PROGRAM, AND EN-*
 24 *ROLLMENT FEES.*—

25 “(1) *ELIGIBILITY AND ELECTION OF PROGRAM.*—

1 “(A) *IN GENERAL.*—Subject to the suc-
 2 ceeding provisions of this paragraph, the enroll-
 3 ment procedures established under section
 4 1807(b)(1)(A)(ii) shall apply for purposes of this
 5 section.

6 “(B) *ENROLLMENT OF ANY ELIGIBLE LOW-*
 7 *INCOME BENEFICIARY.*—Each prescription drug
 8 card sponsor offering a prescription drug assist-
 9 ance card program under this section shall per-
 10 mit any eligible low-income beneficiary to enroll
 11 in such program if it serves the geographic area
 12 in which the beneficiary resides.

13 “(C) *SIMULTANEOUS ENROLLMENT IN PRE-*
 14 *SCRIPTION DRUG DISCOUNT CARD PROGRAM.*—
 15 An eligible low-income beneficiary who enrolls in
 16 a prescription drug assistance card program of-
 17 fered by a prescription drug card sponsor under
 18 this section shall be simultaneously enrolled in a
 19 prescription drug discount card program offered
 20 by such sponsor.

21 “(2) *WAIVER OF ENROLLMENT FEES.*—

22 “(A) *IN GENERAL.*—A prescription drug
 23 card sponsor may not charge an enrollment fee
 24 to any eligible low-income beneficiary enrolled in

1 *a prescription drug discount card program of-*
 2 *fered by such sponsor.*

3 “(B) *PAYMENT BY SECRETARY.*—*Under a*
 4 *contract awarded under subsection (f)(2), the*
 5 *Secretary shall pay to each prescription drug*
 6 *card sponsor an amount equal to any enrollment*
 7 *fee charged under section 1807(b)(2)(A) on behalf*
 8 *of each eligible low-income beneficiary enrolled*
 9 *in a prescription drug discount card program*
 10 *under paragraph (1)(C) offered by such sponsor.*

11 “(c) *ADDITIONAL BENEFICIARY PROTECTIONS.*—

12 “(1) *PROVIDING INFORMATION TO ELIGIBLE*
 13 *LOW-INCOME BENEFICIARIES.*—*In addition to the in-*
 14 *formation provided to eligible beneficiaries under sec-*
 15 *tion 1807(c), the prescription drug card sponsor*
 16 *shall—*

17 “(A) *periodically notify each eligible low-in-*
 18 *come beneficiary enrolled in a prescription drug*
 19 *assistance card program offered by such sponsor*
 20 *of the amount of coverage for prescription drugs*
 21 *remaining under subsection (d)(2)(A); and*

22 “(B) *notify each eligible low-income bene-*
 23 *ficiary enrolled in a prescription drug assistance*
 24 *card program offered by such sponsor of the*

1 *grievance and appeals processes under the pro-*
2 *gram.*

3 “(2) *CONVENIENT ACCESS IN LONG-TERM CARE*
4 *FACILITIES.*—*For purposes of determining whether*
5 *convenient access has been provided under section*
6 *1807(d)(2) with respect to eligible low-income bene-*
7 *ficiaries enrolled in a prescription drug assistance*
8 *card program, the Secretary may only make a deter-*
9 *mination that such access has been provided if an ap-*
10 *propriate arrangement is in place for eligible low-in-*
11 *come beneficiaries who are in a long-term care facil-*
12 *ity (as defined by the Secretary) to receive prescrip-*
13 *tion drug benefits under the program.*

14 “(3) *COORDINATION OF BENEFITS.*—

15 “(A) *IN GENERAL.*—*The Secretary shall es-*
16 *tablish procedures under which eligible low-in-*
17 *come beneficiaries who are enrolled for coverage*
18 *described in subparagraph (B) and enrolled in a*
19 *prescription drug assistance card program have*
20 *access to the prescription drug benefits available*
21 *under such program.*

22 “(B) *COVERAGE DESCRIBED.*—*Coverage de-*
23 *scribed in this subparagraph is as follows:*

1 “(i) Coverage of prescription drugs
2 under a State pharmaceutical assistance
3 program.

4 “(ii) Enrollment in a
5 Medicare+Choice plan under part C.

6 “(4) GRIEVANCE MECHANISM.—Each prescrip-
7 tion drug card sponsor with a contract under this sec-
8 tion shall provide in accordance with section 1852(f)
9 meaningful procedures for hearing and resolving
10 grievances between the prescription drug card sponsor
11 (including any entity or individual through which
12 the prescription drug card sponsor provides covered
13 benefits) and enrollees in a prescription drug assist-
14 ance card program offered by such sponsor.

15 “(5) APPLICATION OF COVERAGE DETERMINA-
16 TION AND RECONSIDERATION PROVISIONS.—

17 “(A) IN GENERAL.—The requirements of
18 paragraphs (1) through (3) of section 1852(g)
19 shall apply with respect to covered benefits under
20 a prescription drug assistance card program
21 under this section in the same manner as such
22 requirements apply to a Medicare+Choice orga-
23 nization with respect to benefits it offers under
24 a Medicare+Choice plan under part C.

1 “(B) *REQUEST FOR REVIEW OF TIERED*
2 *FORMULARY DETERMINATIONS.*—*In the case of a*
3 *prescription drug assistance card program of-*
4 *fered by a prescription drug card sponsor that*
5 *provides for tiered pricing for drugs included*
6 *within a formulary and provides lower prices for*
7 *preferred drugs included within the formulary,*
8 *an eligible low-income beneficiary who is en-*
9 *rolled in the program may request coverage of a*
10 *nonpreferred drug under the terms applicable for*
11 *preferred drugs if the prescribing physician de-*
12 *termines that the preferred drug for treatment of*
13 *the same condition is not as effective for the eli-*
14 *gible low-income beneficiary or has adverse ef-*
15 *fects for the eligible low-income beneficiary.*

16 “(C) *FORMULARY DETERMINATIONS.*—*An*
17 *eligible low-income beneficiary who is enrolled in*
18 *a prescription drug assistance card program of-*
19 *fered by a prescription drug card sponsor may*
20 *appeal to obtain coverage for a covered drug that*
21 *is not on a formulary of the entity if the pre-*
22 *scribing physician determines that the formulary*
23 *drug for treatment of the same condition is not*
24 *as effective for the eligible low-income beneficiary*

1 or has adverse effects for the eligible low-income
2 beneficiary.

3 “(6) *APPEALS*.—

4 “(A) *IN GENERAL*.—Subject to subpara-
5 graph (B), a prescription drug card sponsor
6 shall meet the requirements of paragraphs (4)
7 and (5) of section 1852(g) with respect to drugs
8 not included on any formulary in a similar
9 manner (as determined by the Secretary) as such
10 requirements apply to a Medicare+Choice orga-
11 nization with respect to benefits it offers under
12 a Medicare+Choice plan under part C.

13 “(B) *FORMULARY DETERMINATIONS*.—An
14 eligible low-income beneficiary who is enrolled in
15 a prescription drug assistance card program of-
16 fered by a prescription drug card sponsor may
17 appeal to obtain coverage for a covered drug that
18 is not on a formulary of the entity if the pre-
19 scribing physician determines that the formulary
20 drug for treatment of the same condition is not
21 as effective for the eligible low-income beneficiary
22 or has adverse effects for the eligible low-income
23 beneficiary.

24 “(C) *APPEALS AND EXCEPTIONS TO APPLI-*
25 *CATION*.—The prescription drug card sponsor

1 *must have, as part of the appeals process under*
 2 *this paragraph, a process for timely appeals for*
 3 *denials of coverage based on the application of*
 4 *the formulary.*

5 “(d) *PRESCRIPTION DRUG BENEFITS.*—

6 “(1) *IN GENERAL.*—Subject to paragraph (5), all
 7 *the benefits available under a prescription drug dis-*
 8 *count card program offered by a prescription drug*
 9 *card sponsor and endorsed under section 1807 shall*
 10 *be available to eligible low-income beneficiaries en-*
 11 *rolled in a prescription drug assistance card program*
 12 *offered by such sponsor.*

13 “(2) *ASSISTANCE FOR ELIGIBLE LOW-INCOME*
 14 *BENEFICIARIES.*—

15 “(A) *\$600 ANNUAL ASSISTANCE.*—Subject to
 16 *subparagraphs (B) and (C) and paragraph (5),*
 17 *each prescription drug card sponsor with a con-*
 18 *tract under this section shall provide coverage for*
 19 *the first \$600 of expenses for prescription drugs*
 20 *incurred during each calendar year by an eligi-*
 21 *ble low-income beneficiary enrolled in a pre-*
 22 *scription drug assistance card program offered*
 23 *by such sponsor.*

24 “(B) *COINSURANCE.*—

1 “(i) *IN GENERAL.*—*The prescription*
2 *drug card sponsor shall determine an*
3 *amount of coinsurance to collect from each*
4 *eligible low-income beneficiary enrolled in a*
5 *prescription drug assistance card program*
6 *offered by such sponsor for which coverage*
7 *is available under subparagraph (A).*

8 “(ii) *AMOUNT.*—*The amount of coin-*
9 *surance collected under clause (i) shall be at*
10 *least 10 percent of the negotiated price of*
11 *each prescription drug dispensed to an eli-*
12 *gible low-income beneficiary.*

13 “(iii) *CONSTRUCTION.*—*Amounts col-*
14 *lected under clause (i) shall not be counted*
15 *against the total amount of coverage avail-*
16 *able under subparagraph (A).*

17 “(C) *REDUCTION FOR LATE ENROLL-*
18 *MENT.*—*For each month during a calendar quar-*
19 *ter in which an eligible low-income beneficiary is*
20 *not enrolled in a prescription drug assistance*
21 *card program offered by a prescription drug*
22 *card sponsor with a contract under this section,*
23 *the amount of assistance available under sub-*
24 *paragraph (A) shall be reduced by \$50.*

1 “(D) *CREDITING OF UNUSED BENEFITS TO-*
 2 *WARD FUTURE YEARS.*—*The dollar amount of*
 3 *coverage described in subparagraph (A) shall be*
 4 *increased by any amount of coverage described*
 5 *in such subparagraph that was not used during*
 6 *the previous calendar year.*

7 “(E) *WAIVER TO ENSURE PROVISION OF*
 8 *BENEFIT.*—*The Secretary may waive such re-*
 9 *quirements of this section and section 1807 as*
 10 *may be necessary to ensure that each eligible*
 11 *low-income beneficiaries has access to the assist-*
 12 *ance described in subparagraph (A).*

13 “(3) *ADDITIONAL DISCOUNTS.*—*A prescription*
 14 *drug card sponsor with a contract under this section*
 15 *shall provide each eligible low-income beneficiary en-*
 16 *rolled in a prescription drug assistance program of-*
 17 *fered by the sponsor with access to negotiated prices*
 18 *that reflect a minimum average discount of at least*
 19 *20 percent of the average wholesale price for prescrip-*
 20 *tion drugs covered under that program.*

21 “(4) *ASSISTANCE CARDS.*—*Each prescription*
 22 *drug card sponsor shall permit eligible low-income*
 23 *beneficiaries enrolled in a prescription drug assist-*
 24 *ance card program offered by such sponsor to use the*

1 *discount card issued under section 1807(e)(4) to ob-*
 2 *tain benefits under the program.*

3 “(5) *APPLICATION OF FORMULARY RESTRIC-*
 4 *TIONS.—A drug prescribed for an eligible low-income*
 5 *beneficiary that would otherwise be a covered drug*
 6 *under this section shall not be so considered under a*
 7 *prescription drug assistance card program if the pro-*
 8 *gram excludes the drug under a formulary and such*
 9 *exclusion is not successfully resolved under paragraph*
 10 *(4), (5), or (6) of subsection (c).*

11 “(e) *REQUIREMENTS FOR PRESCRIPTION DRUG CARD*
 12 *SPONSORS THAT OFFER PRESCRIPTION DRUG ASSISTANCE*
 13 *CARD PROGRAMS.—*

14 “(1) *IN GENERAL.—Each prescription drug card*
 15 *sponsor shall—*

16 “(A) *process claims made by eligible low-in-*
 17 *come beneficiaries;*

18 “(B) *negotiate with brand name and ge-*
 19 *neric prescription drug manufacturers and oth-*
 20 *ers for low prices on prescription drugs;*

21 “(C) *track individual beneficiary expendi-*
 22 *tures in a format and periodicity specified by*
 23 *the Secretary; and*

24 “(D) *perform such other functions as the*
 25 *Secretary may assign.*

1 “(2) *DATA EXCHANGES.*—*Each prescription drug*
 2 *card sponsor shall receive data exchanges in a format*
 3 *specified by the Secretary and shall maintain real-*
 4 *time beneficiary files.*

5 “(3) *PUBLIC DISCLOSURE OF PHARMACEUTICAL*
 6 *PRICES FOR EQUIVALENT DRUGS.*—*The prescription*
 7 *drug card sponsor offering the prescription drug as-*
 8 *stance card program shall provide that each phar-*
 9 *macy or other dispenser that arranges for the dis-*
 10 *persing of a covered drug shall inform the eligible*
 11 *low-income beneficiary at the time of purchase of the*
 12 *drug of any differential between the price of the pre-*
 13 *scribed drug to the enrollee and the price of the lowest*
 14 *priced generic drug covered under the plan that is*
 15 *therapeutically equivalent and bioequivalent and*
 16 *available at such pharmacy or other dispenser.*

17 “(f) *SUBMISSION OF BIDS AND AWARDING OF CON-*
 18 *TRACTS.*—

19 “(1) *SUBMISSION OF BIDS.*—*Each prescription*
 20 *drug card sponsor that seeks to offer a prescription*
 21 *drug assistance card program under this section shall*
 22 *submit to the Secretary, at such time and in such*
 23 *manner as the Secretary may specify, such informa-*
 24 *tion as the Secretary may require.*

1 “(2) *AWARDING OF CONTRACTS.*—*The Secretary*
2 *shall review the information submitted under para-*
3 *graph (1) and shall determine whether to award a*
4 *contract to the prescription drug card sponsor offer-*
5 *ing the program to which such information relates.*
6 *The Secretary may not approve a program unless the*
7 *program and prescription drug card sponsor offering*
8 *the program comply with the requirements under this*
9 *section.*

10 “(3) *NUMBER OF CONTRACTS.*—*There shall be no*
11 *limit on the number of prescription drug card spon-*
12 *sors that may be awarded contracts under paragraph*
13 *(2).*

14 “(4) *CONTRACT PROVISIONS.*—

15 “(A) *DURATION.*—*A contract awarded*
16 *under paragraph (2) shall be for the lifetime of*
17 *the program under this section.*

18 “(B) *WITHDRAWAL.*—*A prescription drug*
19 *card sponsor that desires to terminate the con-*
20 *tract awarded under paragraph (2) may termi-*
21 *nate such contract without penalty if such spon-*
22 *sor gives notice—*

23 “(i) *to the Secretary 90 days prior to*
24 *the termination of such contract; and*

1 “(ii) to each eligible low-income bene-
 2 ficiary that is enrolled in a prescription
 3 drug assistance card program offered by
 4 such sponsor 60 days prior to such termi-
 5 nation.

6 “(C) SERVICE AREA.—The service area
 7 under the contract shall be the same as the area
 8 served by the prescription drug card sponsor
 9 under section 1807.

10 “(5) SIMULTANEOUS APPROVAL OF DISCOUNT
 11 CARD AND ASSISTANCE PROGRAMS.—A prescription
 12 drug card sponsor may submit an application for en-
 13 dorsement under section 1807 as part of the bid sub-
 14 mitted under paragraph (1) and the Secretary may
 15 approve such application at the same time as the Sec-
 16 retary awards a contract under this section.

17 “(g) PAYMENTS TO PRESCRIPTION DRUG CARD SPON-
 18 SORS.—

19 “(1) IN GENERAL.—The Secretary shall pay to
 20 each prescription drug card sponsor offering a pre-
 21 scription drug assistance card program in which an
 22 eligible low-income beneficiary is enrolled an amount
 23 equal to the amount agreed to by the Secretary and
 24 the sponsor in the contract awarded under subsection
 25 (f)(2).

1 “(2) *PAYMENT FROM PART B TRUST FUND.*—*The*
 2 *costs of providing benefits under this section shall be*
 3 *payable from the Federal Supplementary Medical In-*
 4 *surance Trust Fund established under section 1841.*

5 “(h) *ELIGIBILITY DETERMINATIONS MADE BY STATES;*
 6 *PRESUMPTIVE ELIGIBILITY.*—*States shall perform the func-*
 7 *tions described in section 1935(a)(1).*

8 “(i) *APPROPRIATIONS.*—*There are appropriated from*
 9 *the Federal Supplementary Medical Insurance Trust Fund*
 10 *established under section 1841 such sums as may be nec-*
 11 *essary to carry out the program under this section.*

12 “(j) *DEFINITIONS.*—*In this section:*

13 “(1) *ELIGIBLE BENEFICIARY; NEGOTIATED*
 14 *PRICE; PRESCRIPTION DRUG.*—*The terms ‘eligible ben-*
 15 *eficiary’, ‘negotiated price’, and ‘prescription drug’*
 16 *have the meanings given those terms in section*
 17 *1807(i).*

18 “(2) *ELIGIBLE LOW-INCOME BENEFICIARY.*—*The*
 19 *term ‘eligible low-income beneficiary’ means an indi-*
 20 *vidual who—*

21 “(A) *is an eligible beneficiary (as defined in*
 22 *section 1807(i)); and*

23 “(B) *is described in clause (iii) or (iv) of*
 24 *section 1902(a)(10)(E) or in section 1905(p)(1).*

1 “(3) *PRESCRIPTION DRUG CARD SPONSOR*.—The
 2 term ‘prescription drug card sponsor’ has the mean-
 3 ing given that term in section 1807(i), except that
 4 such sponsor shall also be an entity that the Secretary
 5 determines is—

6 “(A) is appropriate to provide eligible low-
 7 income beneficiaries with the benefits under a
 8 prescription drug assistance card program under
 9 this section; and

10 “(B) is able to manage the monetary assist-
 11 ance made available under subsection (d)(2);

12 “(C) agrees to submit to audits by the Sec-
 13 retary; and

14 “(D) provides such other assurances as the
 15 Secretary may require.

16 “(4) *STATE*.—The term ‘State’ has the meaning
 17 given such term for purposes of title XIX.”.

18 (b) *EXCLUSION OF PRICES FROM DETERMINATION OF*
 19 *BEST PRICE*.—Section 1927(c)(1)(C)(i) (42 U.S.C. 1396r-
 20 8(c)(1)(C)(i)) is amended—

21 (1) by striking “and” at the end of subclause
 22 (III);

23 (2) by striking the period at the end of subclause
 24 (IV) and inserting “; and”; and

1 (3) *by adding at the end the following new sub-*
 2 *clause:*

3 “(V) *any negotiated prices*
 4 *charged under the medicare prescrip-*
 5 *tion drug discount card endorsement*
 6 *program under section 1807 or under*
 7 *the transitional prescription drug as-*
 8 *stance card program for eligible low-*
 9 *income beneficiaries under section*
 10 *1807A.”.*

11 (c) *EXCLUSION OF PRESCRIPTION DRUG ASSISTANCE*
 12 *CARD COSTS FROM DETERMINATION OF PART B MONTHLY*
 13 *PREMIUM.—Section 1839(g) of the Social Security Act (42*
 14 *U.S.C. 1395r(g)) is amended—*

15 (1) *by striking “attributable to the application of*
 16 *section” and inserting “attributable to—*

17 *“(1) the application of section”;*

18 (2) *by striking the period and inserting “; and”;*

19 *and*

20 (3) *by adding at the end the following new para-*
 21 *graph:*

22 *“(2) the prescription drug assistance card pro-*
 23 *gram under section 1807A.”.*

24 (d) *REGULATIONS.—*

1 (1) *AUTHORITY FOR INTERIM FINAL REGULA-*
 2 *TIONS.—The Secretary may promulgate initial regu-*
 3 *lations implementing sections 1807 and 1807A of the*
 4 *Social Security Act (as added by this section) in in-*
 5 *terim final form without prior opportunity for public*
 6 *comment.*

7 (2) *FINAL REGULATIONS.—A final regulation re-*
 8 *flecting public comments must be published within 1*
 9 *year of the interim final regulation promulgated*
 10 *under paragraph (1).*

11 (3) *EXEMPTION FROM THE PAPERWORK REDUC-*
 12 *TION ACT.—The promulgation of the regulations*
 13 *under this subsection and the administration the pro-*
 14 *grams established by sections 1807 and 1807A of the*
 15 *Social Security Act (as added by this section) shall*
 16 *be made without regard to chapter 35 of title 44,*
 17 *United States Code (commonly known as the “Paper-*
 18 *work Reduction Act”).*

19 (e) *IMPLEMENTATION; TRANSITION.—*

20 (1) *IMPLEMENTATION.—The Secretary shall im-*
 21 *plement the amendments made by this section in a*
 22 *manner that discounts are available to eligible bene-*
 23 *ficiaries under section 1807 of the Social Security Act*
 24 *and assistance is available to eligible low-income*

1 *beneficiaries under section 1807A of such Act not*
 2 *later than January 1, 2004.*

3 (2) *TRANSITION.—The Secretary shall provide*
 4 *for an appropriate transition and discontinuation of*
 5 *the programs under section 1807 and 1807A of the*
 6 *Social Security Act. Such transition and discontinu-*
 7 *ation shall ensure that such programs continue to op-*
 8 *erate until the date on which the first enrollment pe-*
 9 *riod under part D ends.*

10 ***Subtitle C—Standards for***
 11 ***Electronic Prescribing***

12 ***SEC. 121. STANDARDS FOR ELECTRONIC PRESCRIBING.***

13 *Title XI (42 U.S.C. 1301 et seq.) is amended by adding*
 14 *at the end the following new part:*

15 *“PART D—ELECTRONIC PRESCRIBING*

16 *“STANDARDS FOR ELECTRONIC PRESCRIBING*

17 *“SEC. 1180. (a) STANDARDS.—*

18 *“(1) DEVELOPMENT AND ADOPTION.—*

19 *“(A) IN GENERAL.—The Secretary shall de-*
 20 *velop or adopt standards for transactions and*
 21 *data elements for such transactions (in this sec-*
 22 *tion referred to as ‘standards’) to enable the elec-*
 23 *tronic transmission of medication history, eligi-*
 24 *bility, benefit, and other prescription informa-*
 25 *tion.*

1 “(B) *CONSULTATION.*—*In developing and*
2 *adopting the standards under subparagraph (A),*
3 *the Secretary shall consult with representatives*
4 *of physicians, hospitals, pharmacists, standard*
5 *setting organizations, pharmacy benefit man-*
6 *agers, beneficiary information exchange net-*
7 *works, technology experts, and representatives of*
8 *the Departments of Veterans Affairs and Defense*
9 *and other interested parties.*

10 “(2) *OBJECTIVE.*—*Any standards developed or*
11 *adopted under this part shall be consistent with the*
12 *objectives of improving—*

13 “(A) *patient safety; and*

14 “(B) *the quality of care provided to pa-*
15 *tients.*

16 “(3) *REQUIREMENTS.*—*Any standards developed*
17 *or adopted under this part shall comply with the fol-*
18 *lowing:*

19 “(A) *PATIENT MAY REQUEST A WRITTEN*
20 *PRESCRIPTION.*—*The standards provide that—*

21 “(i) *a prescription shall be written and*
22 *not transmitted electronically if the patient*
23 *makes such a request; and*

1 “(ii) *no additional charges may be im-*
 2 *posed on the patient for making such a re-*
 3 *quest.*

4 “(B) *PATIENT-SPECIFIC MEDICATION HIS-*
 5 *TORY, ELIGIBILITY, BENEFIT, AND OTHER PRE-*
 6 *SCRIPTION INFORMATION.—*

7 “(i) *IN GENERAL.—The standards shall*
 8 *accommodate electronic transmittal of pa-*
 9 *tient-specific medication history, eligibility,*
 10 *benefit, and other prescription information*
 11 *among prescribing and dispensing profes-*
 12 *sionals at the point of care.*

13 “(ii) *REQUIRED INFORMATION.—The*
 14 *information described in clause (i) shall in-*
 15 *clude the following:*

16 “(I) *Information (to the extent*
 17 *available and feasible) on the drugs*
 18 *being prescribed for that patient and*
 19 *other information relating to the medi-*
 20 *cation history of the patient that may*
 21 *be relevant to the appropriate prescrip-*
 22 *tion for that patient.*

23 “(II) *Cost-effective alternatives (if*
 24 *any) to the drug prescribed.*

1 “(III) *Information on eligibility*
2 *and benefits, including the drugs in-*
3 *cluded in the applicable formulary and*
4 *any requirements for prior authoriza-*
5 *tion.*

6 “(IV) *Information on potential*
7 *interactions with drugs listed on the*
8 *medication history, graded by severity*
9 *of the potential interaction.*

10 “(V) *Other information to im-*
11 *prove the quality of patient care and*
12 *to reduce medical errors.*

13 “(C) *UNDUE BURDEN.—The standards shall*
14 *be designed so that, to the extent practicable, the*
15 *standards do not impose an undue administra-*
16 *tive burden on the practice of medicine, phar-*
17 *macy, or other health professions.*

18 “(D) *COMPATIBILITY WITH ADMINISTRATIVE*
19 *SIMPLIFICATION AND PRIVACY LAWS.—The stand-*
20 *ards shall be—*

21 “(i) *consistent with the Federal regula-*
22 *tions (concerning the privacy of individ-*
23 *ually identifiable health information) pro-*
24 *mulgated under section 264(c) of the Health*

1 *Insurance Portability and Accountability*
2 *Act of 1996; and*

3 “(ii) *compatible with the standards*
4 *adopted under part C.*

5 “(4) *TRANSFER OF INFORMATION.—The Sec-*
6 *retary shall develop and adopt standards for transfer-*
7 *ring among prescribing and insurance entities and*
8 *other necessary entities appropriate standard data*
9 *elements needed for the electronic exchange of medica-*
10 *tion history, eligibility, benefit, and other prescrip-*
11 *tion drug information and other health information*
12 *determined appropriate in compliance with the*
13 *standards adopted or modified under this part.*

14 “(b) *TIMETABLE FOR ADOPTION OF STANDARDS.—*

15 “(1) *IN GENERAL.—The Secretary shall adopt*
16 *the standards under this part by January 1, 2006.*

17 “(2) *ADDITIONS AND MODIFICATIONS TO STAND-*
18 *ARDS.—The Secretary shall, in consultation with ap-*
19 *propriate representatives of interested parties, review*
20 *the standards developed or adopted under this part*
21 *and adopt modifications to the standards (including*
22 *additions to the standards), as determined appro-*
23 *priate. Any addition or modification to such stand-*
24 *ards shall be completed in a manner which minimizes*
25 *the disruption and cost of compliance.*

1 “(c) *COMPLIANCE WITH STANDARDS.*—

2 “(1) *REQUIREMENT FOR ALL INDIVIDUALS AND*
 3 *ENTITIES THAT TRANSMIT OR RECEIVE PRESCRIP-*
 4 *TIONS ELECTRONICALLY.*—

5 “(A) *IN GENERAL.*—*Individuals or entities*
 6 *that transmit or receive prescriptions electroni-*
 7 *cally shall comply with the standards adopted or*
 8 *modified under this part.*

9 “(B) *RELATION TO STATE LAWS.*—*The*
 10 *standards adopted or modified under this part*
 11 *shall supersede any State law or regulations per-*
 12 *taining to the electronic transmission of medica-*
 13 *tion history, eligibility, benefit and prescription*
 14 *information.*

15 “(2) *TIMETABLE FOR COMPLIANCE.*—

16 “(A) *INITIAL COMPLIANCE.*—

17 “(i) *IN GENERAL.*—*Not later than 24*
 18 *months after the date on which an initial*
 19 *standard is adopted under this part, each*
 20 *individual or entity to whom the standard*
 21 *applies shall comply with the standard.*

22 “(ii) *SPECIAL RULE FOR SMALL*
 23 *HEALTH PLANS.*—*In the case of a small*
 24 *health plan, as defined by the Secretary for*
 25 *purposes of section 1175(b)(1)(B), clause (i)*

1 *shall be applied by substituting ‘36 months’*
2 *for ‘24 months’.*

3 “(d) *CONSULTATION WITH ATTORNEY GENERAL.—The*
4 *Secretary shall consult with the Attorney General before de-*
5 *veloping, adopting, or modifying a standard under this*
6 *part to ensure that the standard accommodates secure elec-*
7 *tronic transmission of prescriptions for controlled sub-*
8 *stances in a manner that minimizes the possibility of viola-*
9 *tions under the Comprehensive Drug Abuse Prevention and*
10 *Control Act of 1970 and related Federal laws.*

11 “(e) *NO REQUIREMENT TO TRANSMIT OR RECEIVE*
12 *PRESCRIPTIONS ELECTRONICALLY.—Nothing in this part*
13 *shall be construed to require an individual or entity to*
14 *transmit or receive prescriptions electronically.*

15 “GRANTS TO HEALTH CARE PROVIDERS TO IMPLEMENT
16 *ELECTRONIC PRESCRIPTION PROGRAMS*

17 “SEC. 1180A. (a) *IN GENERAL.—The Secretary is au-*
18 *thorized to make grants to health care providers for the pur-*
19 *pose of assisting such entities to implement electronic pre-*
20 *scription programs that comply with the standards adopted*
21 *or modified under this part.*

22 “(b) *APPLICATION.—No grant may be made under this*
23 *section except pursuant to a grant application that is sub-*
24 *mitted in a time, manner, and form approved by the Sec-*
25 *retary.*

1 “(c) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*
 2 *authorized to be appropriated for each of fiscal years 2006,*
 3 *2007, and 2008, such sums as may be necessary to carry*
 4 *out this section.*”.

5 ***Subtitle D—Other Provisions***

6 ***SEC. 131. ADDITIONAL REQUIREMENTS FOR ANNUAL FI-***
 7 ***NANCIAL REPORT AND OVERSIGHT ON MEDI-***
 8 ***CARE PROGRAM.***

9 (a) *IN GENERAL.*—*Section 1817 (42 U.S.C. 1395i) is*
 10 *amended by adding at the end the following new subsection:*

11 “(l) *COMBINED REPORT ON OPERATION AND STATUS*
 12 *OF THE TRUST FUND AND THE FEDERAL SUPPLEMENTARY*
 13 *MEDICAL INSURANCE TRUST FUND (INCLUDING THE PRE-*
 14 *SCRIPTION DRUG ACCOUNT).*—*In addition to the duty of*
 15 *the Board of Trustees to report to Congress under subsection*
 16 *(b), on the date the Board submits the report required under*
 17 *subsection (b)(2), the Board shall submit to Congress a re-*
 18 *port on the operation and status of the Trust Fund and*
 19 *the Federal Supplementary Medical Insurance Trust Fund*
 20 *established under section 1841 (including the Prescription*
 21 *Drug Account within such Trust Fund), in this subsection*
 22 *referred to as the ‘Trust Funds’. Such report shall include*
 23 *the following information:*

24 “(1) *OVERALL SPENDING FROM THE GENERAL*
 25 *FUND OF THE TREASURY.*—*A statement of total*

1 *amounts obligated during the preceding fiscal year*
 2 *from the General Revenues of the Treasury to the*
 3 *Trust Funds, separately stated in terms of the total*
 4 *amount and in terms of the percentage such amount*
 5 *bears to all other amounts obligated from such Gen-*
 6 *eral Revenues during such fiscal year, for each of the*
 7 *following amounts:*

8 “(A) *MEDICARE BENEFITS.*—*The amount*
 9 *expended for payment of benefits covered under*
 10 *this title.*

11 “(B) *ADMINISTRATIVE AND OTHER EX-*
 12 *PENSES.*—*The amount expended for payments*
 13 *not related to the benefits described in subpara-*
 14 *graph (A).*

15 “(2) *HISTORICAL OVERVIEW OF SPENDING.*—
 16 *From the date of the inception of the program of in-*
 17 *surance under this title through the fiscal year in-*
 18 *volved, a statement of the total amounts referred to in*
 19 *paragraph (1), separately stated for the amounts de-*
 20 *scribed in subparagraphs (A) and (B) of such para-*
 21 *graph.*

22 “(3) *10-YEAR AND 50-YEAR PROJECTIONS.*—*An*
 23 *estimate of total amounts referred to in paragraph*
 24 *(1), separately stated for the amounts described in*
 25 *subparagraphs (A) and (B) of such paragraph, re-*

1 *quired to be obligated for payment for benefits covered*
 2 *under this title for each of the 10 fiscal years suc-*
 3 *ceeding the fiscal year involved and for the 50-year*
 4 *period beginning with the succeeding fiscal year.*

5 *“(4) RELATION TO OTHER MEASURES OF*
 6 *GROWTH.—A comparison of the rate of growth of the*
 7 *total amounts referred to in paragraph (1), separately*
 8 *stated for the amounts described in subparagraphs*
 9 *(A) and (B) of such paragraph, to the rate of growth*
 10 *for the same period in—*

11 *“(A) the gross domestic product;*

12 *“(B) health insurance costs in the private*
 13 *sector;*

14 *“(C) employment-based health insurance*
 15 *costs in the public and private sectors; and*

16 *“(D) other areas as determined appropriate*
 17 *by the Board of Trustees.”.*

18 *(b) EFFECTIVE DATE.—The amendment made by sub-*
 19 *section (a) shall apply with respect to fiscal years beginning*
 20 *on or after the date of enactment of this Act.*

21 *(c) CONGRESSIONAL HEARINGS.—It is the sense of*
 22 *Congress that the committees of jurisdiction of Congress*
 23 *shall hold hearings on the reports submitted under section*
 24 *1817(l) of the Social Security Act (as added by subsection*
 25 *(a)).*

1 **SEC. 132. TRUSTEES' REPORT ON MEDICARE'S UNFUNDED**
 2 **OBLIGATIONS.**

3 (a) *REPORT.*—The report submitted under sections
 4 1817(b)(2) and 1841(b)(2) of the Social Security Act (42
 5 U.S.C. 1395i(b)(2) and 1395t(b)(2)) during 2004 shall in-
 6 clude an analysis of the total amount of the unfunded obli-
 7 gations of the Medicare program under title XVIII of the
 8 Social Security Act.

9 (b) *MATTERS ANALYZED.*—The analysis described in
 10 subsection (A) shall compare the long-term obligations of
 11 the Medicare program to the dedicated funding sources for
 12 that program (other than general revenue transfers), includ-
 13 ing the combined obligations of the Federal Hospital Insur-
 14 ance Trust Fund established under section 1817 of such Act
 15 (42 U.S.C. 1395i) and the Federal Supplementary Medical
 16 Insurance Trust Fund established under section 1841 of
 17 such Act (42 U.S.C. 1395t).

18 **SEC. 133. PHARMACY BENEFIT MANAGERS TRANSPARENCY**
 19 **REQUIREMENTS.**

20 Subpart 3 of part D of title XVIII of the Social Secu-
 21 rity Act (as added by section 101) is amended by adding
 22 at the end the following new section:

23 “PHARMACY BENEFIT MANAGERS TRANSPARENCY
 24 REQUIREMENTS

25 “SEC. 1860D–27. (a) *PROHIBITION.*—

1 “(1) *IN GENERAL.*—Notwithstanding any other
 2 *provision of law, an eligible entity offering a Medi-*
 3 *care Prescription Drug plan under this part or a*
 4 *MedicareAdvantage organization offering a*
 5 *MedicareAdvantage plan under part C shall not enter*
 6 *into a contract with any pharmacy benefit manager*
 7 *(in this section referred to as a ‘PBM’) that is owned*
 8 *by a pharmaceutical manufacturing company.*

9 “(2) *PROVISION OF INFORMATION.*—A PBM that
 10 *manages prescription drug coverage under this part*
 11 *or part C shall provide the following information, on*
 12 *an annual basis, to the Assistant Attorney General*
 13 *for Antitrust of the Department of Justice and the In-*
 14 *spector General of the Health and Human Services*
 15 *Department:*

16 “(A) *The aggregate amount of any and all*
 17 *rebates, discounts, administrative fees, pro-*
 18 *motional allowances, and other payments re-*
 19 *ceived or recovered from each pharmaceutical*
 20 *manufacturer.*

21 “(B) *The amount of payments received or*
 22 *recovered from each pharmaceutical manufac-*
 23 *turer for each of the top 50 drugs as measured*
 24 *by volume (as determined by the Secretary).*

1 “(C) *The percentage differential between the*
 2 *price the PBM pays pharmacies for a drug de-*
 3 *scribed in subparagraph (B) and the price the*
 4 *PBM charges a Medicare Prescription Drug*
 5 *Plan or a MedicareAdvantage organization for*
 6 *such drug.*

7 “(b) *FAILURE TO DISCLOSE.—*

8 “(1) *CIVIL PENALTY.—Any PBM that fails to*
 9 *comply with subsection (a) shall be liable for a civil*
 10 *penalty as determined appropriate through regula-*
 11 *tions promulgated by the Attorney General. Such pen-*
 12 *alty may be recovered in a civil action brought by the*
 13 *United States.*

14 “(2) *COMPLIANCE AND EQUITABLE RELIEF.—If*
 15 *any PBM fails to comply with subsection (a), the*
 16 *United States district court may order compliance,*
 17 *and may grant such other equitable relief as the court*
 18 *in its discretion determines necessary or appropriate,*
 19 *upon application of the Assistant Attorney General.*

20 “(c) *DISCLOSURE EXEMPTION.—Any information*
 21 *filed with the Assistant Attorney General under subsection*
 22 *(a)(2) shall be exempt from disclosure under section 552*
 23 *of title 5, and no such information may be made public,*
 24 *except as may be relevant to any administrative or judicial*
 25 *action or proceeding. Nothing in this section is intended*

1 *to prevent disclosure to either body of Congress or to any*
 2 *duly authorized committee or subcommittee of the Con-*
 3 *gress.”.*

4 **SEC. 134. OFFICE OF THE MEDICARE BENEFICIARY ADVOCATE.**
 5

6 *(a) ESTABLISHMENT.—Not later than 1 year after the*
 7 *date of enactment of this Act, the Secretary shall establish*
 8 *within the Department of Health and Human Services, an*
 9 *Office of the Medicare Beneficiary Advocate (in this section*
 10 *referred to as the “Office”).*

11 *(b) DUTIES.—The Office shall carry out the following*
 12 *activities:*

13 *(1) Establishing a toll-free telephone number for*
 14 *medicare beneficiaries to use to obtain information on*
 15 *the medicare program, and particularly with respect*
 16 *to the benefits provided under part D of title XVIII*
 17 *of the Social Security Act and the Medicare Prescrip-*
 18 *tion Drug plans and MedicareAdvantage plans offer-*
 19 *ing such benefits. The Office shall ensure that the toll-*
 20 *free telephone number accommodates beneficiaries*
 21 *with disabilities and limited-English proficiency.*

22 *(2) Establishing an Internet website with easily*
 23 *accessible information regarding Medicare Prescrip-*
 24 *tion Drug plans and MedicareAdvantage plans and*

1 *the benefits offered under such plans. The website*
2 *shall—*

3 *(A) be updated regularly to reflect changes*
4 *in services and benefits, including with respect to*
5 *the plans offered in a region and the associated*
6 *monthly premiums, benefits offered, formularies,*
7 *and contact information for such plans, and to*
8 *ensure that there are no broken links or errors;*

9 *(B) have printer-friendly, downloadable fact*
10 *sheets on the medicare coverage options and ben-*
11 *efits;*

12 *(C) be easy to navigate, with large print*
13 *and easily recognizable links; and*

14 *(D) provide links to the websites of the eligi-*
15 *ble entities participating in part D of title*
16 *XVIII.*

17 *(3) Providing regional publications to medicare*
18 *beneficiaries that include regional contacts for infor-*
19 *mation, and that inform the beneficiaries of the pre-*
20 *scription drug benefit options under title XVIII of the*
21 *Social Security Act, including with respect to—*

22 *(A) monthly premiums;*

23 *(B) formularies; and*

24 *(C) the scope of the benefits offered.*

1 (4) *Conducting outreach to medicare bene-*
 2 *ficiaries to inform the beneficiaries of the medicare*
 3 *coverage options and benefits under parts A, B, C,*
 4 *and D of title XVIII of the Social Security Act.*

5 (5) *Working with local benefits administrators,*
 6 *ombudsmen, local benefits specialists, and advocacy*
 7 *groups to ensure that medicare beneficiaries are*
 8 *aware of the medicare coverage options and benefits*
 9 *under parts A, B, C, and D of title XVIII of the So-*
 10 *cial Security Act.*

11 (c) *FUNDING.*—

12 (1) *ESTABLISHMENT.*—*Of the amounts author-*
 13 *ized to be appropriated under the Secretary's discre-*
 14 *tion for administrative expenditures, \$2,000,000 may*
 15 *be used to establish the Office in accordance with this*
 16 *section.*

17 (2) *OPERATION.*—*With respect to each fiscal*
 18 *year occurring after the fiscal year in which the Of-*
 19 *fice is established under this section, the Secretary*
 20 *may use, out of amounts authorized to be appro-*
 21 *priated under the Secretary's discretion for adminis-*
 22 *trative expenditures for such fiscal year, such sums as*
 23 *may be necessary to operate the Office in that fiscal*
 24 *year.*

1 ***TITLE II—MEDICAREADVANTAGE***
 2 ***Subtitle A—MedicareAdvantage***
 3 ***Competition***

4 ***SEC. 201. ELIGIBILITY, ELECTION, AND ENROLLMENT.***

5 *Section 1851 (42 U.S.C. 1395w–21) is amended to*
 6 *read as follows:*

7 *“ELIGIBILITY, ELECTION, AND ENROLLMENT*

8 *“SEC. 1851. (a) CHOICE OF MEDICARE BENEFITS*
 9 *THROUGH MEDICAREADVANTAGE PLANS.—*

10 *“(1) IN GENERAL.—Subject to the provisions of*
 11 *this section, each MedicareAdvantage eligible indi-*
 12 *vidual (as defined in paragraph (3)) is entitled to*
 13 *elect to receive benefits under this title—*

14 *“(A) through—*

15 *“(i) the original Medicare fee-for-serv-*
 16 *ice program under parts A and B; and*

17 *“(ii) the voluntary prescription drug*
 18 *delivery program under part D; or*

19 *“(B) through enrollment in a*
 20 *MedicareAdvantage plan under this part.*

21 *“(2) TYPES OF MEDICAREADVANTAGE PLANS*
 22 *THAT MAY BE AVAILABLE.—A MedicareAdvantage*
 23 *plan may be any of the following types of plans of*
 24 *health insurance:*

1 “(A) *COORDINATED CARE PLANS.*—Coordi-
 2 nated care plans which provide health care serv-
 3 ices, including health maintenance organization
 4 plans (with or without point of service options)
 5 and plans offered by provider-sponsored organi-
 6 zations (as defined in section 1855(d)).

7 “(B) *COMBINATION OF MSA PLAN AND CON-*
 8 *TRIBUTIONS TO MEDICAREADVANTAGE MSA.*—An
 9 MSA plan, as defined in section 1859(b)(3), and
 10 a contribution into a MedicareAdvantage med-
 11 ical savings account (MSA).

12 “(C) *PRIVATE FEE-FOR-SERVICE PLANS.*—A
 13 MedicareAdvantage private fee-for-service plan,
 14 as defined in section 1859(b)(2).

15 “(3) *MEDICAREADVANTAGE ELIGIBLE INDIV-*
 16 *VIDUAL.*—

17 “(A) *IN GENERAL.*—Subject to subpara-
 18 graph (B), in this title, the term
 19 ‘MedicareAdvantage eligible individual’ means
 20 an individual who is entitled to (or enrolled for)
 21 benefits under part A, enrolled under part B,
 22 and enrolled under part D.

23 “(B) *SPECIAL RULE FOR END-STAGE RENAL*
 24 *DISEASE.*—Such term shall not include an indi-

vidual medically determined to have end-stage renal disease, except that—

“(i) an individual who develops end-stage renal disease while enrolled in a Medicare+Choice or a MedicareAdvantage plan may continue to be enrolled in that plan; and

“(ii) in the case of such an individual who is enrolled in a Medicare+Choice plan or a MedicareAdvantage plan under clause (i) (or subsequently under this clause), if the enrollment is discontinued under circumstances described in section 1851(e)(4)(A), then the individual will be treated as a ‘MedicareAdvantage eligible individual’ for purposes of electing to continue enrollment in another MedicareAdvantage plan.

“(b) *SPECIAL RULES.*—

“(1) *RESIDENCE REQUIREMENT.*—

“(A) *IN GENERAL.*—Except as the Secretary may otherwise provide and except as provided in subparagraph (C), an individual is eligible to elect a MedicareAdvantage plan offered by a MedicareAdvantage organization only if the plan

1 serves the geographic area in which the indi-
2 vidual resides.

3 “(B) CONTINUATION OF ENROLLMENT PER-
4 MITTED.—Pursuant to rules specified by the Sec-
5 retary, the Secretary shall provide that a plan
6 may offer to all individuals residing in a geo-
7 graphic area the option to continue enrollment
8 in the plan, notwithstanding that the individual
9 no longer resides in the service area of the plan,
10 so long as the plan provides that individuals ex-
11 ercising this option have, as part of the basic
12 benefits described in section 1852(a)(1)(A), rea-
13 sonable access within that geographic area to the
14 full range of basic benefits, subject to reasonable
15 cost-sharing liability in obtaining such benefits.

16 “(C) CONTINUATION OF ENROLLMENT PER-
17 MITTED WHERE SERVICE CHANGED.—Notwith-
18 standing subparagraph (A) and in addition to
19 subparagraph (B), if a MedicareAdvantage orga-
20 nization eliminates from its service area a
21 MedicareAdvantage payment area that was pre-
22 viously within its service area, the organization
23 may elect to offer individuals residing in all or
24 portions of the affected area who would otherwise
25 be ineligible to continue enrollment the option to

1 *continue enrollment in a MedicareAdvantage*
 2 *plan it offers so long as—*

3 “(i) *the enrollee agrees to receive the*
 4 *full range of basic benefits (excluding emer-*
 5 *gency and urgently needed care) exclusively*
 6 *at facilities designated by the organization*
 7 *within the plan service area; and*

8 “(ii) *there is no other*
 9 *MedicareAdvantage plan offered in the area*
 10 *in which the enrollee resides at the time of*
 11 *the organization’s election.*

12 “(2) *SPECIAL RULE FOR CERTAIN INDIVIDUALS*
 13 *COVERED UNDER FEHBP OR ELIGIBLE FOR VETERANS*
 14 *OR MILITARY HEALTH BENEFITS.—*

15 “(A) *FEHBP.—An individual who is en-*
 16 *rolled in a health benefit plan under chapter 89*
 17 *of title 5, United States Code, is not eligible to*
 18 *enroll in an MSA plan until such time as the*
 19 *Director of the Office of Management and Budget*
 20 *certifies to the Secretary that the Office of Per-*
 21 *sonnel Management has adopted policies which*
 22 *will ensure that the enrollment of such individ-*
 23 *uals in such plans will not result in increased*
 24 *expenditures for the Federal Government for*
 25 *health benefit plans under such chapter.*

1 “(B) VA AND DOD.—*The Secretary may*
 2 *apply rules similar to the rules described in sub-*
 3 *paragraph (A) in the case of individuals who are*
 4 *eligible for health care benefits under chapter 55*
 5 *of title 10, United States Code, or under chapter*
 6 *17 of title 38 of such Code.*

7 “(3) *LIMITATION ON ELIGIBILITY OF QUALIFIED*
 8 *MEDICARE BENEFICIARIES AND OTHER MEDICAID*
 9 *BENEFICIARIES TO ENROLL IN AN MSA PLAN.*—*An in-*
 10 *dividual who is a qualified medicare beneficiary (as*
 11 *defined in section 1905(p)(1)), a qualified disabled*
 12 *and working individual (described in section*
 13 *1905(s)), an individual described in section*
 14 *1902(a)(10)(E)(iii), or otherwise entitled to medicare*
 15 *cost-sharing under a State plan under title XIX is*
 16 *not eligible to enroll in an MSA plan.*

17 “(4) *COVERAGE UNDER MSA PLANS ON A DEM-*
 18 *ONSTRATION BASIS.*—

19 “(A) *IN GENERAL.*—*An individual is not el-*
 20 *igible to enroll in an MSA plan under this*
 21 *part—*

22 “(i) *on or after January 1, 2004, un-*
 23 *less the enrollment is the continuation of*
 24 *such an enrollment in effect as of such date;*
 25 *or*

1 “(ii) as of any date if the number of
 2 such individuals so enrolled as of such date
 3 has reached 390,000.

4 Under rules established by the Secretary, an in-
 5 dividual is not eligible to enroll (or continue en-
 6 rollment) in an MSA plan for a year unless the
 7 individual provides assurances satisfactory to the
 8 Secretary that the individual will reside in the
 9 United States for at least 183 days during the
 10 year.

11 “(B) EVALUATION.—The Secretary shall
 12 regularly evaluate the impact of permitting en-
 13 rollment in MSA plans under this part on selec-
 14 tion (including adverse selection), use of preven-
 15 tive care, access to care, and the financial status
 16 of the Trust Funds under this title.

17 “(C) REPORTS.—The Secretary shall submit
 18 to Congress periodic reports on the numbers of
 19 individuals enrolled in such plans and on the
 20 evaluation being conducted under subparagraph
 21 (B).

22 “(c) PROCESS FOR EXERCISING CHOICE.—

23 “(1) IN GENERAL.—The Secretary shall establish
 24 a process through which elections described in sub-
 25 section (a) are made and changed, including the form

1 *and manner in which such elections are made and*
 2 *changed. Such elections shall be made or changed only*
 3 *during coverage election periods specified under sub-*
 4 *section (e) and shall become effective as provided in*
 5 *subsection (f).*

6 “(2) COORDINATION THROUGH
 7 *MEDICAREADVANTAGE ORGANIZATIONS.—*

8 “(A) *ENROLLMENT.—Such process shall*
 9 *permit an individual who wishes to elect a*
 10 *MedicareAdvantage plan offered by a*
 11 *MedicareAdvantage organization to make such*
 12 *election through the filing of an appropriate elec-*
 13 *tion form with the organization.*

14 “(B) *DISENROLLMENT.—Such process shall*
 15 *permit an individual, who has elected a*
 16 *MedicareAdvantage plan offered by a*
 17 *MedicareAdvantage organization and who wishes*
 18 *to terminate such election, to terminate such elec-*
 19 *tion through the filing of an appropriate election*
 20 *form with the organization.*

21 “(3) *DEFAULT.—*

22 “(A) *INITIAL ELECTION.—*

23 “(i) *IN GENERAL.—Subject to clause*
 24 *(ii), an individual who fails to make an*
 25 *election during an initial election period*

1 under subsection (e)(1) is deemed to have
2 chosen the original medicare fee-for-service
3 program option.

4 “(ii) SEAMLESS CONTINUATION OF
5 COVERAGE.—The Secretary may establish
6 procedures under which an individual who
7 is enrolled in a Medicare+Choice plan or
8 another health plan (other than a
9 MedicareAdvantage plan) offered by a
10 MedicareAdvantage organization at the
11 time of the initial election period and who
12 fails to elect to receive coverage other than
13 through the organization is deemed to have
14 elected the MedicareAdvantage plan offered
15 by the organization (or, if the organization
16 offers more than 1 such plan, such plan or
17 plans as the Secretary identifies under such
18 procedures).

19 “(B) CONTINUING PERIODS.—An individual
20 who has made (or is deemed to have made) an
21 election under this section is considered to have
22 continued to make such election until such time
23 as—

24 “(i) the individual changes the election
25 under this section; or

1 “(ii) the MedicareAdvantage plan with
 2 respect to which such election is in effect is
 3 discontinued or, subject to subsection
 4 (b)(1)(B), no longer serves the area in
 5 which the individual resides.

6 “(d) PROVIDING INFORMATION TO PROMOTE IN-
 7 FORMED CHOICE.—

8 “(1) IN GENERAL.—The Secretary shall provide
 9 for activities under this subsection to broadly dissemi-
 10 nate information to medicare beneficiaries (and pro-
 11 spective medicare beneficiaries) on the coverage op-
 12 tions provided under this section in order to promote
 13 an active, informed selection among such options.

14 “(2) PROVISION OF NOTICE.—

15 “(A) OPEN SEASON NOTIFICATION.—At least
 16 15 days before the beginning of each annual, co-
 17 ordinated election period (as defined in sub-
 18 section (e)(3)(B)), the Secretary shall mail to
 19 each MedicareAdvantage eligible individual re-
 20 siding in an area the following:

21 “(i) GENERAL INFORMATION.—The
 22 general information described in paragraph
 23 (3).

24 “(ii) LIST OF PLANS AND COMPARISON
 25 OF PLAN OPTIONS.—A list identifying the

1 *MedicareAdvantage plans that are (or will*
 2 *be) available to residents of the area and in-*
 3 *formation described in paragraph (4) con-*
 4 *cerning such plans. Such information shall*
 5 *be presented in a comparative form.*

6 “(iii) *ADDITIONAL INFORMATION.—*
 7 *Any other information that the Secretary*
 8 *determines will assist the individual in*
 9 *making the election under this section.*

10 *The mailing of such information shall be coordi-*
 11 *nated, to the extent practicable, with the mailing*
 12 *of any annual notice under section 1804.*

13 “(B) *NOTIFICATION TO NEWLY ELIGIBLE*
 14 *MEDICAREADVANTAGE ELIGIBLE INDIVIDUALS.—*
 15 *To the extent practicable, the Secretary shall, not*
 16 *later than 30 days before the beginning of the*
 17 *initial MedicareAdvantage enrollment period for*
 18 *an individual described in subsection (e)(1),*
 19 *mail to the individual the information described*
 20 *in subparagraph (A).*

21 “(C) *FORM.—The information disseminated*
 22 *under this paragraph shall be written and for-*
 23 *matted using language that is easily understand-*
 24 *able by medicare beneficiaries.*

1 “(D) *PERIODIC UPDATING.*—*The informa-*
 2 *tion described in subparagraph (A) shall be up-*
 3 *dated on at least an annual basis to reflect*
 4 *changes in the availability of MedicareAdvantage*
 5 *plans, the benefits under such plans, and the*
 6 *MedicareAdvantage monthly basic beneficiary*
 7 *premium, MedicareAdvantage monthly bene-*
 8 *ficiary premium for enhanced medical benefits,*
 9 *and MedicareAdvantage monthly beneficiary ob-*
 10 *ligation for qualified prescription drug coverage*
 11 *for such plans.*

12 “(3) *GENERAL INFORMATION.*—*General informa-*
 13 *tion under this paragraph, with respect to coverage*
 14 *under this part during a year, shall include the fol-*
 15 *lowing:*

16 “(A) *BENEFITS UNDER THE ORIGINAL*
 17 *MEDICARE FEE-FOR-SERVICE PROGRAM OP-*
 18 *TION.*—*A general description of the benefits cov-*
 19 *ered under parts A and B of the original medi-*
 20 *care fee-for-service program, including—*

21 “(i) *covered items and services;*

22 “(ii) *beneficiary cost-sharing, such as*
 23 *deductibles, coinsurance, and copayment*
 24 *amounts; and*

1 “(iii) *any beneficiary liability for bal-*
2 *ance billing.*

3 “(B) *CATASTROPHIC COVERAGE AND COM-*
4 *BINED DEDUCTIBLE.—A description of the cata-*
5 *strophic coverage and unified deductible applica-*
6 *ble under the plan.*

7 “(C) *OUTPATIENT PRESCRIPTION DRUG*
8 *COVERAGE BENEFITS.—The information required*
9 *under section 1860D–4 with respect to coverage*
10 *for prescription drugs under the plan.*

11 “(D) *ELECTION PROCEDURES.—Informa-*
12 *tion and instructions on how to exercise election*
13 *options under this section.*

14 “(E) *RIGHTS.—A general description of*
15 *procedural rights (including grievance and ap-*
16 *peals procedures) of beneficiaries under the origi-*
17 *nal medicare fee-for-service program (including*
18 *such rights under part D) and the*
19 *MedicareAdvantage program and the right to be*
20 *protected against discrimination based on health*
21 *status-related factors under section 1852(b).*

22 “(F) *INFORMATION ON MEDIGAP AND MEDI-*
23 *CARE SELECT.—A general description of the ben-*
24 *efits, enrollment rights, and other requirements*
25 *applicable to medicare supplemental policies*

1 *under section 1882 and provisions relating to*
 2 *medicare select policies described in section*
 3 *1882(t).*

4 “(G) *POTENTIAL FOR CONTRACT TERMI-*
 5 *NATION.—The fact that a MedicareAdvantage or-*
 6 *ganization may terminate its contract, refuse to*
 7 *renew its contract, or reduce the service area in-*
 8 *cluded in its contract, under this part, and the*
 9 *effect of such a termination, nonrenewal, or serv-*
 10 *ice area reduction may have on individuals en-*
 11 *rolled with the MedicareAdvantage plan under*
 12 *this part.*

13 “(4) *INFORMATION COMPARING PLAN OPTIONS.—*
 14 *Information under this paragraph, with respect to a*
 15 *MedicareAdvantage plan for a year, shall include the*
 16 *following:*

17 “(A) *BENEFITS.—The benefits covered*
 18 *under the plan, including the following:*

19 “(i) *Covered items and services beyond*
 20 *those provided under the original medicare*
 21 *fee-for-service program option.*

22 “(ii) *Beneficiary cost-sharing for any*
 23 *items and services described in clause (i)*
 24 *and paragraph (3)(A)(i), including infor-*

1 *mation on the unified deductible under sec-*
2 *tion 1852(a)(1)(C).*

3 “(iii) *The maximum limitations on*
4 *out-of-pocket expenses under section*
5 *1852(a)(1)(C).*

6 “(iv) *In the case of an MSA plan, dif-*
7 *ferences in cost-sharing, premiums, and bal-*
8 *ance billing under such a plan compared to*
9 *under other MedicareAdvantage plans.*

10 “(v) *In the case of a*
11 *MedicareAdvantage private fee-for-service*
12 *plan, differences in cost-sharing, premiums,*
13 *and balance billing under such a plan com-*
14 *pared to under other MedicareAdvantage*
15 *plans.*

16 “(vi) *The extent to which an enrollee*
17 *may obtain benefits through out-of-network*
18 *health care providers.*

19 “(vii) *The extent to which an enrollee*
20 *may select among in-network providers and*
21 *the types of providers participating in the*
22 *plan’s network.*

23 “(viii) *The organization’s coverage of*
24 *emergency and urgently needed care.*

1 “(ix) *The comparative information de-*
 2 *scribed in section 1860D–4(b)(2) relating to*
 3 *prescription drug coverage under the plan.*

4 “(B) *PREMIUMS.—*

5 “(i) *IN GENERAL.—The*
 6 *MedicareAdvantage monthly basic bene-*
 7 *ficiary premium and MedicareAdvantage*
 8 *monthly beneficiary premium for enhanced*
 9 *medical benefits, if any, for the plan or, in*
 10 *the case of an MSA plan, the*
 11 *MedicareAdvantage monthly MSA pre-*
 12 *mium.*

13 “(ii) *REDUCTIONS.—The reduction in*
 14 *part B premiums, if any.*

15 “(iii) *NATURE OF THE PREMIUM FOR*
 16 *ENHANCED MEDICAL BENEFITS.—Whether*
 17 *the MedicareAdvantage monthly premium*
 18 *for enhanced benefits is optional or manda-*
 19 *tory.*

20 “(C) *SERVICE AREA.—The service area of*
 21 *the plan.*

22 “(D) *QUALITY AND PERFORMANCE.—Plan*
 23 *quality and performance indicators for the bene-*
 24 *fits under the plan (and how such indicators*
 25 *compare to quality and performance indicators*

under the original medicare fee-for-service program under parts A and B and under the voluntary prescription drug delivery program under part D in the area involved), including—

“(i) disenrollment rates for medicare enrollees electing to receive benefits through the plan for the previous 2 years (excluding disenrollment due to death or moving outside the plan’s service area);

“(ii) information on medicare enrollee satisfaction;

“(iii) information on health outcomes; and

“(iv) the recent record regarding compliance of the plan with requirements of this part (as determined by the Secretary).

“(5) *MAINTAINING A TOLL-FREE NUMBER AND INTERNET SITE.*—The Secretary shall maintain a toll-free number for inquiries regarding MedicareAdvantage options and the operation of this part in all areas in which MedicareAdvantage plans are offered and an Internet site through which individuals may electronically obtain information on such options and MedicareAdvantage plans.

1 “(6) *USE OF NON-FEDERAL ENTITIES.*—*The Sec-*
 2 *retary may enter into contracts with non-Federal en-*
 3 *tities to carry out activities under this subsection.*

4 “(7) *PROVISION OF INFORMATION.*—*A*
 5 *MedicareAdvantage organization shall provide the*
 6 *Secretary with such information on the organization*
 7 *and each MedicareAdvantage plan it offers as may be*
 8 *required for the preparation of the information re-*
 9 *ferred to in paragraph (2)(A).*

10 “(e) *COVERAGE ELECTION PERIODS.*—

11 “(1) *INITIAL CHOICE UPON ELIGIBILITY TO MAKE*
 12 *ELECTION IF MEDICAREADVANTAGE PLANS AVAILABLE*
 13 *TO INDIVIDUAL.*—*If, at the time an individual first*
 14 *becomes eligible to elect to receive benefits under part*
 15 *B or D (whichever is later), there is 1 or more*
 16 *MedicareAdvantage plans offered in the area in which*
 17 *the individual resides, the individual shall make the*
 18 *election under this section during a period specified*
 19 *by the Secretary such that if the individual elects a*
 20 *MedicareAdvantage plan during the period, coverage*
 21 *under the plan becomes effective as of the first date*
 22 *on which the individual may receive such coverage.*

23 “(2) *OPEN ENROLLMENT AND DISENROLLMENT*
 24 *OPPORTUNITIES.*—*Subject to paragraph (5), the fol-*
 25 *lowing rules shall apply:*

1 “(A) *CONTINUOUS OPEN ENROLLMENT AND*
 2 *DISENROLLMENT THROUGH 2005.*—*At any time*
 3 *during the period beginning January 1, 1998,*
 4 *and ending on December 31, 2005, a*
 5 *Medicare+Choice eligible individual may change*
 6 *the election under subsection (a)(1).*

7 “(B) *CONTINUOUS OPEN ENROLLMENT AND*
 8 *DISENROLLMENT FOR FIRST 6 MONTHS DURING*
 9 *2006.*—

10 “(i) *IN GENERAL.*—*Subject to clause*
 11 *(ii) and subparagraph (D), at any time*
 12 *during the first 6 months of 2006, or, if the*
 13 *individual first becomes a*
 14 *MedicareAdvantage eligible individual dur-*
 15 *ing 2006, during the first 6 months during*
 16 *2006 in which the individual is a*
 17 *MedicareAdvantage eligible individual, a*
 18 *MedicareAdvantage eligible individual may*
 19 *change the election under subsection (a)(1).*

20 “(ii) *LIMITATION OF 1 CHANGE.*—*An*
 21 *individual may exercise the right under*
 22 *clause (i) only once. The limitation under*
 23 *this clause shall not apply to changes in*
 24 *elections effected during an annual, coordi-*
 25 *nated election period under paragraph (3)*

1 or during a special enrollment period under
2 the first sentence of paragraph (4).

3 “(C) *CONTINUOUS OPEN ENROLLMENT AND*
4 *DISENROLLMENT FOR FIRST 3 MONTHS IN SUB-*
5 *SEQUENT YEARS.—*

6 “(i) *IN GENERAL.—Subject to clause*
7 *(ii) and subparagraph (D), at any time*
8 *during the first 3 months of 2007 and each*
9 *subsequent year, or, if the individual first*
10 *becomes a MedicareAdvantage eligible indi-*
11 *vidual during 2007 or any subsequent year,*
12 *during the first 3 months of such year in*
13 *which the individual is a*
14 *MedicareAdvantage eligible individual, a*
15 *MedicareAdvantage eligible individual may*
16 *change the election under subsection (a)(1).*

17 “(ii) *LIMITATION OF 1 CHANGE DURING*
18 *OPEN ENROLLMENT PERIOD EACH YEAR.—*
19 *An individual may exercise the right under*
20 *clause (i) only once during the applicable 3-*
21 *month period described in such clause in*
22 *each year. The limitation under this clause*
23 *shall not apply to changes in elections ef-*
24 *fecting during an annual, coordinated elec-*
25 *tion period under paragraph (3) or during*

1 *a special enrollment period under para-*
 2 *graph (4).*

3 “(D) *CONTINUOUS OPEN ENROLLMENT FOR*
 4 *INSTITUTIONALIZED INDIVIDUALS.—At any time*
 5 *during 2006 or any subsequent year, in the case*
 6 *of a MedicareAdvantage eligible individual who*
 7 *is institutionalized (as defined by the Secretary),*
 8 *the individual may elect under subsection*
 9 *(a)(1)—*

10 *“(i) to enroll in a MedicareAdvantage*
 11 *plan; or*

12 *“(ii) to change the MedicareAdvantage*
 13 *plan in which the individual is enrolled.*

14 “(3) *ANNUAL, COORDINATED ELECTION PE-*
 15 *RIOD.—*

16 “(A) *IN GENERAL.—Subject to paragraph*
 17 *(5), each individual who is eligible to make an*
 18 *election under this section may change such elec-*
 19 *tion during an annual, coordinated election pe-*
 20 *riod.*

21 “(B) *ANNUAL, COORDINATED ELECTION PE-*
 22 *RIOD.—For purposes of this section, the term*
 23 *‘annual, coordinated election period’ means, with*
 24 *respect to a year before 2003 and after 2006, the*
 25 *month of November before such year and with re-*

1 *spect to 2003, 2004, 2005, and 2006, the period*
 2 *beginning on November 15 and ending on De-*
 3 *cember 31 of the year before such year.*

4 “(C) *MEDICAREADVANTAGE HEALTH INFOR-*
 5 *MATION FAIRS.—During the fall season of each*
 6 *year (beginning with 2006), in conjunction with*
 7 *the annual coordinated election period defined in*
 8 *subparagraph (B), the Secretary shall provide*
 9 *for a nationally coordinated educational and*
 10 *publicity campaign to inform*
 11 *MedicareAdvantage eligible individuals about*
 12 *MedicareAdvantage plans and the election proc-*
 13 *ess provided under this section.*

14 “(D) *SPECIAL INFORMATION CAMPAIGN IN*
 15 *2005.—During the period beginning on November*
 16 *15, 2005, and ending on December 31, 2005, the*
 17 *Secretary shall provide for an educational and*
 18 *publicity campaign to inform*
 19 *MedicareAdvantage eligible individuals about the*
 20 *availability of MedicareAdvantage plans, and el-*
 21 *igible organizations with risk-sharing contracts*
 22 *under section 1876, offered in different areas and*
 23 *the election process provided under this section.*

24 “(4) *SPECIAL ELECTION PERIODS.—Effective on*
 25 *and after January 1, 2006, an individual may dis-*

1 *continue an election of a MedicareAdvantage plan of-*
2 *fered by a MedicareAdvantage organization other*
3 *than during an annual, coordinated election period*
4 *and make a new election under this section if—*

5 “(A)(i) *the certification of the organization*
6 *or plan under this part has been terminated, or*
7 *the organization or plan has notified the indi-*
8 *vidual of an impending termination of such cer-*
9 *tification; or*

10 “(ii) *the organization has terminated or*
11 *otherwise discontinued providing the plan in the*
12 *area in which the individual resides, or has noti-*
13 *fied the individual of an impending termination*
14 *or discontinuation of such plan;*

15 “(B) *the individual is no longer eligible to*
16 *elect the plan because of a change in the individ-*
17 *ual’s place of residence or other change in cir-*
18 *cumstances (specified by the Secretary, but not*
19 *including termination of the individual’s enroll-*
20 *ment on the basis described in clause (i) or (ii)*
21 *of subsection (g)(3)(B));*

22 “(C) *the individual demonstrates (in ac-*
23 *cordance with guidelines established by the Sec-*
24 *retary) that—*

1 “(i) the organization offering the plan
2 substantially violated a material provision
3 of the organization’s contract under this
4 part in relation to the individual (includ-
5 ing the failure to provide an enrollee on a
6 timely basis medically necessary care for
7 which benefits are available under the plan
8 or the failure to provide such covered care
9 in accordance with applicable quality
10 standards); or

11 “(ii) the organization (or an agent or
12 other entity acting on the organization’s be-
13 half) materially misrepresented the plan’s
14 provisions in marketing the plan to the in-
15 dividual; or

16 “(D) the individual meets such other excep-
17 tional conditions as the Secretary may provide.

18 *Effective on and after January 1, 2006, an indi-*
19 *vidual who, upon first becoming eligible for benefits*
20 *under part A at age 65, enrolls in a*
21 *MedicareAdvantage plan under this part, the indi-*
22 *vidual may discontinue the election of such plan, and*
23 *elect coverage under the original fee-for-service plan,*
24 *at any time during the 12-month period beginning on*
25 *the effective date of such enrollment.*

1 “(5) *SPECIAL RULES FOR MSA PLANS.*—Notwith-
 2 standing the preceding provisions of this subsection,
 3 an individual—

4 “(A) may elect an MSA plan only during—

5 “(i) an initial open enrollment period
 6 described in paragraph (1);

7 “(ii) an annual, coordinated election
 8 period described in paragraph (3)(B); or

9 “(iii) the month of November 1998;

10 “(B) subject to subparagraph (C), may not
 11 discontinue an election of an MSA plan except
 12 during the periods described in clause (ii) or
 13 (iii) of subparagraph (A) and under the first
 14 sentence of paragraph (4); and

15 “(C) who elects an MSA plan during an
 16 annual, coordinated election period, and who
 17 never previously had elected such a plan, may
 18 revoke such election, in a manner determined by
 19 the Secretary, by not later than December 15 fol-
 20 lowing the date of the election.

21 “(6) *OPEN ENROLLMENT PERIODS.*—Subject to
 22 paragraph (5), a MedicareAdvantage organization—

23 “(A) shall accept elections or changes to
 24 elections during the initial enrollment periods
 25 described in paragraph (1), during the period be-

1 *ginning on November 15, 2005, and ending on*
 2 *December 31, 2005, and during the annual, co-*
 3 *ordinated election period under paragraph (3)*
 4 *for each subsequent year, and during special*
 5 *election periods described in the first sentence of*
 6 *paragraph (4); and*

7 *“(B) may accept other changes to elections*
 8 *at such other times as the organization provides.*

9 *“(f) EFFECTIVENESS OF ELECTIONS AND CHANGES OF*
 10 *ELECTIONS.—*

11 *“(1) DURING INITIAL COVERAGE ELECTION PE-*
 12 *RIOD.—An election of coverage made during the ini-*
 13 *tial coverage election period under subsection*
 14 *(e)(1)(A) shall take effect upon the date the individual*
 15 *becomes entitled to (or enrolled for) benefits under*
 16 *part A, enrolled under part B, and enrolled under*
 17 *part D, except as the Secretary may provide (con-*
 18 *sistent with sections 1838 and 1860D–2)) in order to*
 19 *prevent retroactive coverage.*

20 *“(2) DURING CONTINUOUS OPEN ENROLLMENT*
 21 *PERIODS.—An election or change of coverage made*
 22 *under subsection (e)(2) shall take effect with the first*
 23 *day of the first calendar month following the date on*
 24 *which the election or change is made.*

1 “(3) *ANNUAL, COORDINATED ELECTION PE-*
 2 *RIOD.—An election or change of coverage made dur-*
 3 *ing an annual, coordinated election period (as defined*
 4 *in subsection (e)(3)(B)) in a year shall take effect as*
 5 *of the first day of the following year.*

6 “(4) *OTHER PERIODS.—An election or change of*
 7 *coverage made during any other period under sub-*
 8 *section (e)(4) shall take effect in such manner as the*
 9 *Secretary provides in a manner consistent (to the ex-*
 10 *tent practicable) with protecting continuity of health*
 11 *benefit coverage.*

12 “(g) *GUARANTEED ISSUE AND RENEWAL.—*

13 “(1) *IN GENERAL.—Except as provided in this*
 14 *subsection, a MedicareAdvantage organization shall*
 15 *provide that at any time during which elections are*
 16 *accepted under this section with respect to a*
 17 *MedicareAdvantage plan offered by the organization,*
 18 *the organization will accept without restrictions indi-*
 19 *viduals who are eligible to make such election.*

20 “(2) *PRIORITY.—If the Secretary determines that*
 21 *a MedicareAdvantage organization, in relation to a*
 22 *MedicareAdvantage plan it offers, has a capacity*
 23 *limit and the number of MedicareAdvantage eligible*
 24 *individuals who elect the plan under this section ex-*
 25 *ceeds the capacity limit, the organization may limit*

1 *the election of individuals of the plan under this sec-*
 2 *tion but only if priority in election is provided—*

3 *“(A) first to such individuals as have elect-*
 4 *ed the plan at the time of the determination; and*

5 *“(B) then to other such individuals in such*
 6 *a manner that does not discriminate, on a basis*
 7 *described in section 1852(b), among the individ-*
 8 *uals (who seek to elect the plan).*

9 *The preceding sentence shall not apply if it would re-*
 10 *sult in the enrollment of enrollees substantially non-*
 11 *representative, as determined in accordance with reg-*
 12 *ulations of the Secretary, of the medicare population*
 13 *in the service area of the plan.*

14 *“(3) LIMITATION ON TERMINATION OF ELEC-*
 15 *TION.—*

16 *“(A) IN GENERAL.—Subject to subpara-*
 17 *graph (B), a MedicareAdvantage organization*
 18 *may not for any reason terminate the election of*
 19 *any individual under this section for a*
 20 *MedicareAdvantage plan it offers.*

21 *“(B) BASIS FOR TERMINATION OF ELEC-*
 22 *TION.—A MedicareAdvantage organization may*
 23 *terminate an individual’s election under this sec-*
 24 *tion with respect to a MedicareAdvantage plan it*
 25 *offers if—*

1 “(i) any MedicareAdvantage monthly
 2 basic beneficiary premium,
 3 MedicareAdvantage monthly beneficiary ob-
 4 ligation for qualified prescription drug cov-
 5 erage, or MedicareAdvantage monthly bene-
 6 ficiary premium for required or optional
 7 enhanced medical benefits required with re-
 8 spect to such plan are not paid on a timely
 9 basis (consistent with standards under sec-
 10 tion 1856 that provide for a grace period
 11 for late payment of such premiums);

12 “(ii) the individual has engaged in
 13 disruptive behavior (as specified in such
 14 standards); or

15 “(iii) the plan is terminated with re-
 16 spect to all individuals under this part in
 17 the area in which the individual resides.

18 “(C) CONSEQUENCE OF TERMINATION.—

19 “(i) TERMINATIONS FOR CAUSE.—Any
 20 individual whose election is terminated
 21 under clause (i) or (ii) of subparagraph (B)
 22 is deemed to have elected to receive benefits
 23 under the original medicare fee-for-service
 24 program option.

1 “(ii) *TERMINATION BASED ON PLAN*
 2 *TERMINATION OR SERVICE AREA REDUC-*
 3 *TION.—Any individual whose election is*
 4 *terminated under subparagraph (B)(iii)*
 5 *shall have a special election period under*
 6 *subsection (e)(4)(A) in which to change cov-*
 7 *erage to coverage under another*
 8 *MedicareAdvantage plan. Such an indi-*
 9 *vidual who fails to make an election during*
 10 *such period is deemed to have chosen to*
 11 *change coverage to the original medicare*
 12 *fee-for-service program option.*

13 “(D) *ORGANIZATION OBLIGATION WITH RE-*
 14 *SPECT TO ELECTION FORMS.—Pursuant to a*
 15 *contract under section 1857858., each*
 16 *MedicareAdvantage organization receiving an*
 17 *election form under subsection (c)(2) shall trans-*
 18 *mit to the Secretary (at such time and in such*
 19 *manner as the Secretary may specify) a copy of*
 20 *such form or such other information respecting*
 21 *the election as the Secretary may specify.*

22 “(h) *APPROVAL OF MARKETING MATERIAL AND APPLI-*
 23 *CATION FORMS.—*

24 “(1) *SUBMISSION.—No marketing material or*
 25 *application form may be distributed by a*

1 *MedicareAdvantage organization to (or for the use of)*
2 *MedicareAdvantage eligible individuals unless—*

3 *“(A) at least 45 days (or 10 days in the*
4 *case described in paragraph (5)) before the date*
5 *of distribution the organization has submitted*
6 *the material or form to the Secretary for review;*
7 *and*

8 *“(B) the Secretary has not disapproved the*
9 *distribution of such material or form.*

10 *“(2) REVIEW.—The standards established under*
11 *section 1856 shall include guidelines for the review of*
12 *any material or form submitted and under such*
13 *guidelines the Secretary shall disapprove (or later re-*
14 *quire the correction of) such material or form if the*
15 *material or form is materially inaccurate or mis-*
16 *leading or otherwise makes a material misrepresenta-*
17 *tion.*

18 *“(3) DEEMED APPROVAL (1-STOP SHOPPING).—*
19 *In the case of material or form that is submitted*
20 *under paragraph (1)(A) to the Secretary or a re-*
21 *gional office of the Department of Health and Human*
22 *Services and the Secretary or the office has not dis-*
23 *approved the distribution of marketing material or*
24 *form under paragraph (1)(B) with respect to a*
25 *MedicareAdvantage plan in an area, the Secretary is*

1 *deemed not to have disapproved such distribution in*
 2 *all other areas covered by the plan and organization*
 3 *except with regard to that portion of such material or*
 4 *form that is specific only to an area involved.*

5 “(4) *PROHIBITION OF CERTAIN MARKETING*
 6 *PRACTICES.—Each MedicareAdvantage organization*
 7 *shall conform to fair marketing standards, in relation*
 8 *to MedicareAdvantage plans offered under this part,*
 9 *included in the standards established under section*
 10 *1856. Such standards—*

11 “(A) *shall not permit a MedicareAdvantage*
 12 *organization to provide for cash or other mone-*
 13 *tary rebates as an inducement for enrollment or*
 14 *otherwise (other than as an additional benefit*
 15 *described in section 1854(g)(1)(C)(i)); and*

16 “(B) *may include a prohibition against a*
 17 *MedicareAdvantage organization (or agent of*
 18 *such an organization) completing any portion of*
 19 *any election form used to carry out elections*
 20 *under this section on behalf of any individual.*

21 “(5) *SPECIAL TREATMENT OF MARKETING MATE-*
 22 *RIAL FOLLOWING MODEL MARKETING LANGUAGE.—In*
 23 *the case of marketing material of an organization*
 24 *that uses, without modification, proposed model lan-*
 25 *guage specified by the Secretary, the period specified*

1 *in paragraph (1)(A) shall be reduced from 45 days to*
 2 *10 days.*

3 “(i) *EFFECT OF ELECTION OF MEDICAREADVANTAGE*
 4 *PLAN OPTION.*—

5 “(1) *PAYMENTS TO ORGANIZATIONS.*—*Subject to*
 6 *sections 1852(a)(5), 1853(h), 1853(i), 1886(d)(11),*
 7 *and 1886(h)(3)(D), payments under a contract with*
 8 *a MedicareAdvantage organization under section*
 9 *1853(a) with respect to an individual electing a*
 10 *MedicareAdvantage plan offered by the organization*
 11 *shall be instead of the amounts which (in the absence*
 12 *of the contract) would otherwise be payable under*
 13 *parts A, B, and D for items and services furnished*
 14 *to the individual.*

15 “(2) *ONLY ORGANIZATION ENTITLED TO PAY-*
 16 *MENT.*—*Subject to sections 1853(f), 1853(h), 1853(i),*
 17 *1857(f)(2), 1886(d)(11), and 1886(h)(3)(D), only the*
 18 *MedicareAdvantage organization shall be entitled to*
 19 *receive payments from the Secretary under this title*
 20 *for services furnished to the individual.”.*

21 **SEC. 202. BENEFITS AND BENEFICIARY PROTECTIONS.**

22 *Section 1852 (42 U.S.C. 1395w–22) is amended to*
 23 *read as follows:*

24 “*BENEFITS AND BENEFICIARY PROTECTIONS*

25 “*SEC. 1852. (a) BASIC BENEFITS.*—

1 “(1) *IN GENERAL.*—*Except as provided in sec-*
 2 *tion 1859(b)(3) for MSA plans, each*
 3 *MedicareAdvantage plan shall provide to members en-*
 4 *rolled under this part, through providers and other*
 5 *persons that meet the applicable requirements of this*
 6 *title and part A of title XI—*

7 “(A) *those items and services (other than*
 8 *hospice care) for which benefits are available*
 9 *under parts A and B to individuals residing in*
 10 *the area served by the plan;*

11 “(B) *except as provided in paragraph*
 12 *(2)(D), qualified prescription drug coverage*
 13 *under part D to individuals residing in the area*
 14 *served by the plan;*

15 “(C) *a maximum limitation on out-of-pock-*
 16 *et expenses and a unified deductible; and*

17 “(D) *additional benefits required under sec-*
 18 *tion 1854(d)(1).*

19 “(2) *SATISFACTION OF REQUIREMENT.*—

20 “(A) *IN GENERAL.*—*A MedicareAdvantage*
 21 *plan (other than an MSA plan) offered by a*
 22 *MedicareAdvantage organization satisfies para-*
 23 *graph (1)(A), with respect to benefits for items*
 24 *and services furnished other than through a pro-*
 25 *vider or other person that has a contract with*

1 *the organization offering the plan, if the plan*
 2 *provides payment in an amount so that—*

3 *“(i) the sum of such payment amount*
 4 *and any cost-sharing provided for under the*
 5 *plan; is equal to at least*

6 *“(ii) the total dollar amount of pay-*
 7 *ment for such items and services as would*
 8 *otherwise be authorized under parts A and*
 9 *B (including any balance billing permitted*
 10 *under such parts).*

11 *“(B) REFERENCE TO RELATED PROVI-*
 12 *SIONS.—For provisions relating to—*

13 *“(i) limitations on balance billing*
 14 *against MedicareAdvantage organizations*
 15 *for noncontract providers, see sections*
 16 *1852(k) and 1866(a)(1)(O); and*

17 *“(ii) limiting actuarial value of en-*
 18 *rollee liability for covered benefits, see sec-*
 19 *tion 1854(f).*

20 *“(C) ELECTION OF UNIFORM COVERAGE*
 21 *POLICY.—In the case of a MedicareAdvantage or-*
 22 *ganization that offers a MedicareAdvantage plan*
 23 *in an area in which more than 1 local coverage*
 24 *policy is applied with respect to different parts*
 25 *of the area, the organization may elect to have*

1 *the local coverage policy for the part of the area*
 2 *that is most beneficial to MedicareAdvantage en-*
 3 *rollees (as identified by the Secretary) apply*
 4 *with respect to all MedicareAdvantage enrollees*
 5 *enrolled in the plan.*

6 *“(D) SPECIAL RULE FOR PRIVATE FEE-FOR-*
 7 *SERVICE PLANS.—*

8 *“(i) IN GENERAL.—A private fee-for-*
 9 *service plan may elect not to provide quali-*
 10 *fied prescription drug coverage under part*
 11 *D to individuals residing in the area served*
 12 *by the plan.*

13 *“(ii) AVAILABILITY OF DRUG COV-*
 14 *ERAGE FOR ENROLLEES.—If a beneficiary*
 15 *enrolls in a plan making the election de-*
 16 *scribed in clause (i), the beneficiary may*
 17 *enroll for drug coverage under part D with*
 18 *an eligible entity under such part.*

19 *“(3) ENHANCED MEDICAL BENEFITS.—*

20 *“(A) BENEFITS INCLUDED SUBJECT TO SEC-*
 21 *RETARY’S APPROVAL.—Each MedicareAdvantage*
 22 *organization may provide to individuals enrolled*
 23 *under this part, other than under an MSA plan*
 24 *(without affording those individuals an option to*
 25 *decline the coverage), enhanced medical benefits*

1 *that the Secretary may approve. The Secretary*
 2 *shall approve any such enhanced medical bene-*
 3 *fits unless the Secretary determines that includ-*
 4 *ing such enhanced medical benefits would sub-*
 5 *stantially discourage enrollment by*
 6 *MedicareAdvantage eligible individuals with the*
 7 *organization.*

8 *“(B) AT ENROLLEES’ OPTION.—A*
 9 *MedicareAdvantage organization may not pro-*
 10 *vide, under an MSA plan, enhanced medical*
 11 *benefits that cover the deductible described in sec-*
 12 *tion 1859(b)(2)(B). In applying the previous*
 13 *sentence, health benefits described in section*
 14 *1882(u)(2)(B) shall not be treated as covering*
 15 *such deductible.*

16 *“(C) APPLICATION TO MEDICAREADVANTAGE*
 17 *PRIVATE FEE-FOR-SERVICE PLANS.—Nothing in*
 18 *this paragraph shall be construed as preventing*
 19 *a MedicareAdvantage private fee-for-service plan*
 20 *from offering enhanced medical benefits that in-*
 21 *clude payment for some or all of the balance bill-*
 22 *ing amounts permitted consistent with section*
 23 *1852(k) and coverage of additional services that*
 24 *the plan finds to be medically necessary.*

1 “(D) *RULE FOR APPROVAL OF MEDICAL AND*
 2 *PRESCRIPTION DRUG BENEFITS.*—*Notwith-*
 3 *standing the preceding provisions of this para-*
 4 *graph, the Secretary may not approve any en-*
 5 *hanced medical benefit that provides for the cov-*
 6 *erage of any prescription drug (other than that*
 7 *relating to prescription drugs covered under the*
 8 *original medicare fee-for-service program op-*
 9 *tion).*

10 “(4) *ORGANIZATION AS SECONDARY PAYER.*—
 11 *Notwithstanding any other provision of law, a*
 12 *MedicareAdvantage organization may (in the case of*
 13 *the provision of items and services to an individual*
 14 *under a MedicareAdvantage plan under cir-*
 15 *cumstances in which payment under this title is*
 16 *made secondary pursuant to section 1862(b)(2))*
 17 *charge or authorize the provider of such services to*
 18 *charge, in accordance with the charges allowed under*
 19 *a law, plan, or policy described in such section—*

20 “(A) *the insurance carrier, employer, or*
 21 *other entity which under such law, plan, or pol-*
 22 *icy is to pay for the provision of such services;*
 23 *or*

1 “(B) such individual to the extent that the
 2 individual has been paid under such law, plan,
 3 or policy for such services.

4 “(5) NATIONAL COVERAGE DETERMINATIONS AND
 5 LEGISLATIVE CHANGES IN BENEFITS.—If there is a
 6 national coverage determination or legislative change
 7 in benefits required to be provided under this part
 8 made in the period beginning on the date of an an-
 9 nouncement under section 1853(b) and ending on the
 10 date of the next announcement under such section and
 11 the Secretary projects that the determination will re-
 12 sult in a significant change in the costs to a
 13 MedicareAdvantage organization of providing the
 14 benefits that are the subject of such national coverage
 15 determination and that such change in costs was not
 16 incorporated in the determination of the benchmark
 17 amount announced under section 1853(b)(1)(A) at the
 18 beginning of such period, then, unless otherwise re-
 19 quired by law—

20 “(A) such determination or legislative
 21 change in benefits shall not apply to contracts
 22 under this part until the first contract year that
 23 begins after the end of such period; and

24 “(B) if such coverage determination or leg-
 25 islative change provides for coverage of addi-

1 *tional benefits or coverage under additional cir-*
 2 *cumstances, section 1851(i)(1) shall not apply to*
 3 *payment for such additional benefits or benefits*
 4 *provided under such additional circumstances*
 5 *until the first contract year that begins after the*
 6 *end of such period.*

7 *The projection under the previous sentence shall be*
 8 *based on an analysis by the Secretary of the actuarial*
 9 *costs associated with the coverage determination or*
 10 *legislative change in benefits.*

11 “(6) *AUTHORITY TO PROHIBIT RISK SELEC-*
 12 *TION.—The Secretary shall have the authority to dis-*
 13 *approve any MedicareAdvantage plan that the Sec-*
 14 *retary determines is designed to attract a population*
 15 *that is healthier than the average population residing*
 16 *in the service area of the plan.*

17 “(7) *UNIFIED DEDUCTIBLE DEFINED.—In this*
 18 *part, the term ‘unified deductible’ means an annual*
 19 *deductible amount that is applied in lieu of the inpa-*
 20 *tient hospital deductible under section 1813(b)(1) and*
 21 *the deductible under section 1833(b). Nothing in this*
 22 *part shall be construed as preventing a*
 23 *MedicareAdvantage organization from requiring coin-*
 24 *surance or a copayment for inpatient hospital serv-*
 25 *ices after the unified deductible is satisfied, subject to*

1 *the limitation on enrollee liability under section*
 2 *1854(f).*

3 “(b) *ANTIDISCRIMINATION.*—

4 “(1) *BENEFICIARIES.*—

5 “(A) *IN GENERAL.*—*A MedicareAdvantage*
 6 *organization may not deny, limit, or condition*
 7 *the coverage or provision of benefits under this*
 8 *part, for individuals permitted to be enrolled*
 9 *with the organization under this part, based on*
 10 *any health status-related factor described in sec-*
 11 *tion 2702(a)(1) of the Public Health Service Act.*

12 “(B) *CONSTRUCTION.*—*Except as provided*
 13 *under section 1851(a)(3)(B), subparagraph (A)*
 14 *shall not be construed as requiring a*
 15 *MedicareAdvantage organization to enroll indi-*
 16 *viduals who are determined to have end-stage*
 17 *renal disease.*

18 “(2) *PROVIDERS.*—*A MedicareAdvantage organi-*
 19 *zation shall not discriminate with respect to partici-*
 20 *pation, reimbursement, or indemnification as to any*
 21 *provider who is acting within the scope of the pro-*
 22 *vider’s license or certification under applicable State*
 23 *law, solely on the basis of such license or certification.*
 24 *This paragraph shall not be construed to prohibit a*
 25 *plan from including providers only to the extent nec-*

1 *essary to meet the needs of the plan’s enrollees or from*
 2 *establishing any measure designed to maintain qual-*
 3 *ity and control costs consistent with the responsibil-*
 4 *ities of the plan.*

5 “(c) *DISCLOSURE REQUIREMENTS.*—

6 “(1) *DETAILED DESCRIPTION OF PLAN PROVI-*
 7 *SIONS.*—A MedicareAdvantage organization shall dis-
 8 *close, in clear, accurate, and standardized form to*
 9 *each enrollee with a MedicareAdvantage plan offered*
 10 *by the organization under this part at the time of en-*
 11 *rollment and at least annually thereafter, the fol-*
 12 *lowing information regarding such plan:*

13 “(A) *SERVICE AREA.*—The plan’s service
 14 *area.*

15 “(B) *BENEFITS.*—Benefits offered under the
 16 *plan, including information described section*
 17 *1852(a)(1) (relating to benefits under the origi-*
 18 *nal medicare fee-for-service program option, the*
 19 *maximum limitation in out-of-pocket expenses*
 20 *and the unified deductible, and qualified pre-*
 21 *scription drug coverage under part D, respec-*
 22 *tively) and exclusions from coverage and, if it is*
 23 *an MSA plan, a comparison of benefits under*
 24 *such a plan with benefits under other*
 25 *MedicareAdvantage plans.*

1 “(C) *ACCESS.*—*The number, mix, and dis-*
 2 *tribution of plan providers, out-of-network cov-*
 3 *erage (if any) provided by the plan, and any*
 4 *point-of-service option (including the*
 5 *MedicareAdvantage monthly beneficiary pre-*
 6 *mium for enhanced medical benefits for such op-*
 7 *tion).*

8 “(D) *OUT-OF-AREA COVERAGE.*—*Out-of-*
 9 *area coverage provided by the plan.*

10 “(E) *EMERGENCY COVERAGE.*—*Coverage of*
 11 *emergency services, including—*

12 “(i) *the appropriate use of emergency*
 13 *services, including use of the 911 telephone*
 14 *system or its local equivalent in emergency*
 15 *situations and an explanation of what con-*
 16 *stitutes an emergency situation;*

17 “(ii) *the process and procedures of the*
 18 *plan for obtaining emergency services; and*

19 “(iii) *the locations of—*

20 “(I) *emergency departments; and*

21 “(II) *other settings, in which plan*
 22 *physicians and hospitals provide emer-*
 23 *gency services and post-stabilization*
 24 *care.*

1 “(F) *ENHANCED MEDICAL BENEFITS.*—*En-*
 2 *hanced medical benefits available from the orga-*
 3 *nization offering the plan, including—*

4 “(i) *whether the enhanced medical ben-*
 5 *efits are optional;*

6 “(ii) *the enhanced medical benefits cov-*
 7 *ered; and*

8 “(iii) *the MedicareAdvantage monthly*
 9 *beneficiary premium for enhanced medical*
 10 *benefits.*

11 “(G) *PRIOR AUTHORIZATION RULES.*—
 12 *Rules regarding prior authorization or other re-*
 13 *view requirements that could result in non-*
 14 *payment.*

15 “(H) *PLAN GRIEVANCE AND APPEALS PRO-*
 16 *CEDURES.*—*All plan appeal or grievance rights*
 17 *and procedures.*

18 “(I) *QUALITY ASSURANCE PROGRAM.*—*A de-*
 19 *scription of the organization’s quality assurance*
 20 *program under subsection (e).*

21 “(2) *DISCLOSURE UPON REQUEST.*—*Upon re-*
 22 *quest of a MedicareAdvantage eligible individual, a*
 23 *MedicareAdvantage organization must provide the fol-*
 24 *lowing information to such individual:*

1 “(A) *The general coverage information and*
 2 *general comparative plan information made*
 3 *available under clauses (i) and (ii) of section*
 4 *1851(d)(2)(A).*

5 “(B) *Information on procedures used by the*
 6 *organization to control utilization of services*
 7 *and expenditures.*

8 “(C) *Information on the number of griev-*
 9 *ances, reconsiderations, and appeals and on the*
 10 *disposition in the aggregate of such matters.*

11 “(D) *An overall summary description as to*
 12 *the method of compensation of participating*
 13 *physicians.*

14 “(E) *The information described in subpara-*
 15 *graphs (A) through (C) in relation to the quali-*
 16 *fied prescription drug coverage provided by the*
 17 *organization.*

18 “(d) *ACCESS TO SERVICES.—*

19 “(1) *IN GENERAL.—A MedicareAdvantage orga-*
 20 *nization offering a MedicareAdvantage plan may se-*
 21 *lect the providers from whom the benefits under the*
 22 *plan are provided so long as—*

23 “(A) *the organization makes such benefits*
 24 *available and accessible to each individual elect-*
 25 *ing the plan within the plan service area with*

1 *reasonable promptness and in a manner which*
2 *assures continuity in the provision of benefits;*

3 *“(B) when medically necessary the organi-*
4 *zation makes such benefits available and acces-*
5 *sible 24 hours a day and 7 days a week;*

6 *“(C) the plan provides for reimbursement*
7 *with respect to services which are covered under*
8 *subparagraphs (A) and (B) and which are pro-*
9 *vided to such an individual other than through*
10 *the organization, if—*

11 *“(i) the services were not emergency*
12 *services (as defined in paragraph (3)),*
13 *but—*

14 *“(I) the services were medically*
15 *necessary and immediately required*
16 *because of an unforeseen illness, injury,*
17 *or condition; and*

18 *“(II) it was not reasonable given*
19 *the circumstances to obtain the services*
20 *through the organization;*

21 *“(ii) the services were renal dialysis*
22 *services and were provided other than*
23 *through the organization because the indi-*
24 *vidual was temporarily out of the plan’s*
25 *service area; or*

1 “(iii) the services are maintenance care
2 or post-stabilization care covered under the
3 guidelines established under paragraph (2);

4 “(D) the organization provides access to ap-
5 propriate providers, including credentialed spe-
6 cialists, for medically necessary treatment and
7 services; and

8 “(E) coverage is provided for emergency
9 services (as defined in paragraph (3)) without
10 regard to prior authorization or the emergency
11 care provider’s contractual relationship with the
12 organization.

13 “(2) *GUIDELINES RESPECTING COORDINATION OF*
14 *POST-STABILIZATION CARE.—A MedicareAdvantage*
15 *plan shall comply with such guidelines as the Sec-*
16 *retary may prescribe relating to promoting efficient*
17 *and timely coordination of appropriate maintenance*
18 *and post-stabilization care of an enrollee after the en-*
19 *rollee has been determined to be stable under section*
20 *1867.*

21 “(3) *DEFINITION OF EMERGENCY SERVICES.—In*
22 *this subsection—*

23 “(A) *IN GENERAL.—The term ‘emergency*
24 *services’ means, with respect to an individual*

enrolled with an organization, covered inpatient
and outpatient services that—

“(i) are furnished by a provider that is
qualified to furnish such services under this
title; and

“(ii) are needed to evaluate or stabilize
an emergency medical condition (as defined
in subparagraph (B)).

“(B) *EMERGENCY MEDICAL CONDITION
BASED ON PRUDENT LAYPERSON.*—The term
‘emergency medical condition’ means a medical
condition manifesting itself by acute symptoms
of sufficient severity (including severe pain) such
that a prudent layperson, who possesses an aver-
age knowledge of health and medicine, could rea-
sonably expect the absence of immediate medical
attention to result in—

“(i) placing the health of the indi-
vidual (or, with respect to a pregnant
woman, the health of the woman or her un-
born child) in serious jeopardy;

“(ii) serious impairment to bodily
functions; or

“(iii) serious dysfunction of any bodily
organ or part.

1 “(4) *ASSURING ACCESS TO SERVICES IN*
2 *MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE*
3 *PLANS.—In addition to any other requirements*
4 *under this part, in the case of a*
5 *MedicareAdvantage private fee-for-service plan,*
6 *the organization offering the plan must dem-*
7 *onstrate to the Secretary that the organization*
8 *has sufficient number and range of health care*
9 *professionals and providers willing to provide*
10 *services under the terms of the plan. The Sec-*
11 *retary shall find that an organization has met*
12 *such requirement with respect to any category of*
13 *health care professional or provider if, with re-*
14 *spect to that category of provider—*

15 “(A) *the plan has established payment*
16 *rates for covered services furnished by that*
17 *category of provider that are not less than*
18 *the payment rates provided for under part*
19 *A, B, or D for such services; or*

20 “(B) *the plan has contracts or agree-*
21 *ments (other than deemed contracts or*
22 *agreements under subsection (j)(6), with a*
23 *sufficient number and range of providers*
24 *within such category to provide covered*
25 *services under the terms of the plan,*

1 or a combination of both. The previous sentence
 2 shall not be construed as restricting the persons
 3 from whom enrollees under such a plan may ob-
 4 tain covered benefits, except that, if a plan en-
 5 tirely meets such requirement with respect to a
 6 category of health care professional or provider
 7 on the basis of subparagraph (B), it may provide
 8 for a higher beneficiary copayment in the case of
 9 health care professionals and providers of that
 10 category who do not have contracts or agree-
 11 ments (other than deemed contracts or agree-
 12 ments under subsection (j)(6)) to provide covered
 13 services under the terms of the plan.

14 “(e) *QUALITY ASSURANCE PROGRAM.*—

15 “(1) *IN GENERAL.*—Each MedicareAdvantage or-
 16 ganization must have arrangements, consistent with
 17 any regulation, for an ongoing quality assurance pro-
 18 gram for health care services it provides to individ-
 19 uals enrolled with MedicareAdvantage plans of the or-
 20 ganization.

21 “(2) *ELEMENTS OF PROGRAM.*—

22 “(A) *IN GENERAL.*—The quality assurance
 23 program of an organization with respect to a
 24 MedicareAdvantage plan (other than a

1 *MedicareAdvantage private fee-for-service plan*
2 *or a nonnetwork MSA plan) it offers shall—*

3 “(i) *stress health outcomes and provide*
4 *for the collection, analysis, and reporting of*
5 *data (in accordance with a quality meas-*
6 *urement system that the Secretary recog-*
7 *nizes) that will permit measurement of out-*
8 *comes and other indices of the quality of*
9 *MedicareAdvantage plans and organiza-*
10 *tions;*

11 “(ii) *monitor and evaluate high vol-*
12 *ume and high risk services and the care of*
13 *acute and chronic conditions;*

14 “(iii) *provide access to disease man-*
15 *agement and chronic care services;*

16 “(iv) *provide access to preventive bene-*
17 *fits and information for enrollees on such*
18 *benefits;*

19 “(v) *evaluate the continuity and co-*
20 *ordination of care that enrollees receive;*

21 “(vi) *be evaluated on an ongoing basis*
22 *as to its effectiveness;*

23 “(vii) *include measures of consumer*
24 *satisfaction;*

1 “(viii) provide the Secretary with such
2 access to information collected as may be
3 appropriate to monitor and ensure the qual-
4 ity of care provided under this part;

5 “(ix) provide review by physicians and
6 other health care professionals of the process
7 followed in the provision of such health care
8 services;

9 “(x) provide for the establishment of
10 written protocols for utilization review,
11 based on current standards of medical prac-
12 tice;

13 “(xi) have mechanisms to detect both
14 underutilization and overutilization of serv-
15 ices;

16 “(xii) after identifying areas for im-
17 provement, establish or alter practice pa-
18 rameters;

19 “(xiii) take action to improve quality
20 and assesses the effectiveness of such action
21 through systematic followup; and

22 “(xiv) make available information on
23 quality and outcomes measures to facilitate
24 beneficiary comparison and choice of health
25 coverage options (in such form and on such

1 *quality and outcomes measures as the Sec-*
 2 *retary determines to be appropriate).*

3 *Such program shall include a separate focus*
 4 *(with respect to all the elements described in this*
 5 *subparagraph) on racial and ethnic minorities.*

6 “(B) *ELEMENTS OF PROGRAM FOR ORGANI-*
 7 *ZATIONS OFFERING MEDICAREADVANTAGE PRI-*
 8 *VATE FEE-FOR-SERVICE PLANS, AND NONNET-*
 9 *WORK MSA PLANS.—The quality assurance pro-*
 10 *gram of an organization with respect to a*
 11 *MedicareAdvantage private fee-for-service plan*
 12 *or a nonnetwork MSA plan it offers shall—*

13 “(i) *meet the requirements of clauses*
 14 *(i) through (viii) of subparagraph (A);*

15 “(ii) *insofar as it provides for the es-*
 16 *tablishment of written protocols for utiliza-*
 17 *tion review, base such protocols on current*
 18 *standards of medical practice; and*

19 “(iii) *have mechanisms to evaluate uti-*
 20 *lization of services and inform providers*
 21 *and enrollees of the results of such evalua-*
 22 *tion.*

23 *Such program shall include a separate focus*
 24 *(with respect to all the elements described in this*
 25 *subparagraph) on racial and ethnic minorities.*

1 “(C) *DEFINITION OF NONNETWORK MSA*
 2 *PLAN.—In this subsection, the term ‘nonnetwork*
 3 *MSA plan’ means an MSA plan offered by a*
 4 *MedicareAdvantage organization that does not*
 5 *provide benefits required to be provided by this*
 6 *part, in whole or in part, through a defined set*
 7 *of providers under contract, or under another ar-*
 8 *rangement, with the organization.*

9 “(3) *EXTERNAL REVIEW.—*

10 “(A) *IN GENERAL.—Each*
 11 *MedicareAdvantage organization shall, for each*
 12 *MedicareAdvantage plan it operates, have an*
 13 *agreement with an independent quality review*
 14 *and improvement organization approved by the*
 15 *Secretary to perform functions of the type de-*
 16 *scribed in paragraphs (4)(B) and (14) of section*
 17 *1154(a) with respect to services furnished by*
 18 *MedicareAdvantage plans for which payment is*
 19 *made under this title. The previous sentence shall*
 20 *not apply to a MedicareAdvantage private fee-*
 21 *for-service plan or a nonnetwork MSA plan that*
 22 *does not employ utilization review.*

23 “(B) *NONDUPLICATION OF ACCREDITA-*
 24 *TION.—Except in the case of the review of qual-*
 25 *ity complaints, and consistent with subpara-*

graph (C), the Secretary shall ensure that the external review activities conducted under subparagraph (A) are not duplicative of review activities conducted as part of the accreditation process.

“(C) *WAIVER AUTHORITY.*—The Secretary may waive the requirement described in subparagraph (A) in the case of an organization if the Secretary determines that the organization has consistently maintained an excellent record of quality assurance and compliance with other requirements under this part.

“(4) *TREATMENT OF ACCREDITATION.*—

“(A) *IN GENERAL.*—The Secretary shall provide that a MedicareAdvantage organization is deemed to meet all the requirements described in any specific clause of subparagraph (B) if the organization is accredited (and periodically re-accredited) by a private accrediting organization under a process that the Secretary has determined assures that the accrediting organization applies and enforces standards that meet or exceed the standards established under section 1856 to carry out the requirements in such clause.

“(B) *REQUIREMENTS DESCRIBED.*—The provisions described in this subparagraph are the following:

“(i) *Paragraphs (1) and (2) of this subsection (relating to quality assurance programs).*

“(ii) *Subsection (b) (relating to anti-discrimination).*

“(iii) *Subsection (d) (relating to access to services).*

“(iv) *Subsection (h) (relating to confidentiality and accuracy of enrollee records).*

“(v) *Subsection (i) (relating to information on advance directives).*

“(vi) *Subsection (j) (relating to provider participation rules).*

“(C) *TIMELY ACTION ON APPLICATIONS.*—The Secretary shall determine, within 210 days after the date the Secretary receives an application by a private accrediting organization and using the criteria specified in section 1865(b)(2), whether the process of the private accrediting organization meets the requirements with respect to any specific clause in subparagraph (B) with

1 *respect to which the application is made. The*
 2 *Secretary may not deny such an application on*
 3 *the basis that it seeks to meet the requirements*
 4 *with respect to only one, or more than one, such*
 5 *specific clause.*

6 “(D) CONSTRUCTION.—*Nothing in this*
 7 *paragraph shall be construed as limiting the au-*
 8 *thority of the Secretary under section 1857, in-*
 9 *cluding the authority to terminate contracts with*
 10 *MedicareAdvantage organizations under sub-*
 11 *section (c)(2) of such section.*

12 “(5) REPORT TO CONGRESS.—

13 “(A) IN GENERAL.—*The Secretary shall*
 14 *submit to Congress a biennial report regarding*
 15 *how quality assurance programs conducted*
 16 *under this subsection focus on racial and ethnic*
 17 *minorities.*

18 “(B) CONTENTS OF REPORT.—*Each such re-*
 19 *port shall include the following:*

20 “(i) *A description of the means by*
 21 *which such programs focus on such racial*
 22 *and ethnic minorities.*

23 “(ii) *An evaluation of the impact of*
 24 *such programs on eliminating health dis-*
 25 *parities and on improving health outcomes,*

1 *continuity and coordination of care, man-*
 2 *agement of chronic conditions, and con-*
 3 *sumer satisfaction.*

4 “(iii) *Recommendations on ways to re-*
 5 *duce clinical outcome disparities among ra-*
 6 *cial and ethnic minorities.*

7 “(f) *GRIEVANCE MECHANISM.—Each*
 8 *MedicareAdvantage organization must provide meaningful*
 9 *procedures for hearing and resolving grievances between the*
 10 *organization (including any entity or individual through*
 11 *which the organization provides health care services) and*
 12 *enrollees with MedicareAdvantage plans of the organization*
 13 *under this part.*

14 “(g) *COVERAGE DETERMINATIONS, RECONSIDER-*
 15 *ATIONS, AND APPEALS.—*

16 “(1) *DETERMINATIONS BY ORGANIZATION.—*

17 “(A) *IN GENERAL.—A MedicareAdvantage*
 18 *organization shall have a procedure for making*
 19 *determinations regarding whether an individual*
 20 *enrolled with the plan of the organization under*
 21 *this part is entitled to receive a health service*
 22 *under this section and the amount (if any) that*
 23 *the individual is required to pay with respect to*
 24 *such service. Subject to paragraph (3), such pro-*

cedures shall provide for such determination to be made on a timely basis.

“(B) *EXPLANATION OF DETERMINATION.*—

Such a determination that denies coverage, in whole or in part, shall be in writing and shall include a statement in understandable language of the reasons for the denial and a description of the reconsideration and appeals processes.

“(2) *RECONSIDERATIONS.*—

“(A) *IN GENERAL.*—The organization shall provide for reconsideration of a determination described in paragraph (1)(B) upon request by the enrollee involved. The reconsideration shall be within a time period specified by the Secretary, but shall be made, subject to paragraph (3), not later than 60 days after the date of the receipt of the request for reconsideration.

“(B) *PHYSICIAN DECISION ON CERTAIN RECONSIDERATIONS.*—A reconsideration relating to a determination to deny coverage based on a lack of medical necessity shall be made only by a physician with appropriate expertise in the field of medicine which necessitates treatment who is other than a physician involved in the initial determination.

1 “(3) *EXPEDITED DETERMINATIONS AND RECON-*
2 *SIDERATIONS.*—

3 “(A) *RECEIPT OF REQUESTS.*—

4 “(i) *ENROLLEE REQUESTS.*—An en-
5 rollee in a MedicareAdvantage plan may re-
6 quest, either in writing or orally, an expe-
7 dited determination under paragraph (1) or
8 an expedited reconsideration under para-
9 graph (2) by the MedicareAdvantage orga-
10 nization.

11 “(ii) *PHYSICIAN REQUESTS.*—A physi-
12 cian, regardless whether the physician is af-
13 filiated with the organization or not, may
14 request, either in writing or orally, such an
15 expedited determination or reconsideration.

16 “(B) *ORGANIZATION PROCEDURES.*—

17 “(i) *IN GENERAL.*—The
18 MedicareAdvantage organization shall
19 maintain procedures for expediting organi-
20 zation determinations and reconsiderations
21 when, upon request of an enrollee, the orga-
22 nization determines that the application of
23 the normal timeframe for making a deter-
24 mination (or a reconsideration involving a
25 determination) could seriously jeopardize

1 *the life or health of the enrollee or the en-*
2 *rollee's ability to regain maximum function.*

3 “(ii) *EXPEDITION REQUIRED FOR PHY-*
4 *SICIAN REQUESTS.—In the case of a request*
5 *for an expedited determination or reconsid-*
6 *eration made under subparagraph (A)(ii),*
7 *the organization shall expedite the deter-*
8 *mination or reconsideration if the request*
9 *indicates that the application of the normal*
10 *timeframe for making a determination (or a*
11 *reconsideration involving a determination)*
12 *could seriously jeopardize the life or health*
13 *of the enrollee or the enrollee's ability to re-*
14 *gain maximum function.*

15 “(iii) *TIMELY RESPONSE.—In cases de-*
16 *scribed in clauses (i) and (ii), the organiza-*
17 *tion shall notify the enrollee (and the physi-*
18 *cian involved, as appropriate) of the deter-*
19 *mination or reconsideration under time*
20 *limitations established by the Secretary, but*
21 *not later than 72 hours of the time of re-*
22 *ceipt of the request for the determination or*
23 *reconsideration (or receipt of the informa-*
24 *tion necessary to make the determination or*

1 reconsideration), or such longer period as
2 the Secretary may permit in specified cases.

3 “(4) *INDEPENDENT REVIEW OF CERTAIN COV-*
4 *ERAGE DENIALS.*—The Secretary shall contract with
5 an independent, outside entity to review and resolve
6 in a timely manner reconsiderations that affirm de-
7 nial of coverage, in whole or in part. The provisions
8 of section 1869(c)(5) shall apply to independent out-
9 side entities under contract with the Secretary under
10 this paragraph.

11 “(5) *APPEALS.*—An enrollee with a
12 MedicareAdvantage plan of a MedicareAdvantage or-
13 ganization under this part who is dissatisfied by rea-
14 son of the enrollee’s failure to receive any health serv-
15 ice to which the enrollee believes the enrollee is enti-
16 tled and at no greater charge than the enrollee believes
17 the enrollee is required to pay is entitled, if the
18 amount in controversy is \$100 or more, to a hearing
19 before the Secretary to the same extent as is provided
20 in section 205(b), and in any such hearing the Sec-
21 retary shall make the organization a party. If the
22 amount in controversy is \$1,000 or more, the indi-
23 vidual or organization shall, upon notifying the other
24 party, be entitled to judicial review of the Secretary’s
25 final decision as provided in section 205(g), and both

1 *the individual and the organization shall be entitled*
 2 *to be parties to that judicial review. In applying sub-*
 3 *sections (b) and (g) of section 205 as provided in this*
 4 *paragraph, and in applying section 205(l) thereto,*
 5 *any reference therein to the Commissioner of Social*
 6 *Security or the Social Security Administration shall*
 7 *be considered a reference to the Secretary or the De-*
 8 *partment of Health and Human Services, respec-*
 9 *tively.*

10 “(h) *CONFIDENTIALITY AND ACCURACY OF ENROLLEE*
 11 *RECORDS.—Insofar as a MedicareAdvantage organization*
 12 *maintains medical records or other health information re-*
 13 *garding enrollees under this part, the MedicareAdvantage*
 14 *organization shall establish procedures—*

15 “(1) *to safeguard the privacy of any individ-*
 16 *ually identifiable enrollee information;*

17 “(2) *to maintain such records and information*
 18 *in a manner that is accurate and timely; and*

19 “(3) *to assure timely access of enrollees to such*
 20 *records and information.*

21 “(i) *INFORMATION ON ADVANCE DIRECTIVES.—Each*
 22 *MedicareAdvantage organization shall meet the requirement*
 23 *of section 1866(f) (relating to maintaining written policies*
 24 *and procedures respecting advance directives).*

25 “(j) *RULES REGARDING PROVIDER PARTICIPATION.—*

1 “(1) *PROCEDURES.—Insofar as a*
2 *MedicareAdvantage organization offers benefits under*
3 *a MedicareAdvantage plan through agreements with*
4 *physicians, the organization shall establish reasonable*
5 *procedures relating to the participation (under an*
6 *agreement between a physician and the organization)*
7 *of physicians under such a plan. Such procedures*
8 *shall include—*

9 “(A) *providing notice of the rules regarding*
10 *participation;*

11 “(B) *providing written notice of participa-*
12 *tion decisions that are adverse to physicians;*
13 *and*

14 “(C) *providing a process within the organi-*
15 *zation for appealing such adverse decisions, in-*
16 *cluding the presentation of information and*
17 *views of the physician regarding such decision.*

18 “(2) *CONSULTATION IN MEDICAL POLICIES.—A*
19 *MedicareAdvantage organization shall consult with*
20 *physicians who have entered into participation agree-*
21 *ments with the organization regarding the organiza-*
22 *tion’s medical policy, quality, and medical manage-*
23 *ment procedures.*

24 “(3) *PROHIBITING INTERFERENCE WITH PRO-*
25 *VIDER ADVICE TO ENROLLEES.—*

1 “(A) *IN GENERAL.*—Subject to subpara-
 2 graphs (B) and (C), a MedicareAdvantage orga-
 3 nization (in relation to an individual enrolled
 4 under a MedicareAdvantage plan offered by the
 5 organization under this part) shall not prohibit
 6 or otherwise restrict a covered health care profes-
 7 sional (as defined in subparagraph (D)) from
 8 advising such an individual who is a patient of
 9 the professional about the health status of the in-
 10 dividual or medical care or treatment for the in-
 11 dividual’s condition or disease, regardless of
 12 whether benefits for such care or treatment are
 13 provided under the plan, if the professional is
 14 acting within the lawful scope of practice.

15 “(B) *CONSCIENCE PROTECTION.*—Subpara-
 16 graph (A) shall not be construed as requiring a
 17 MedicareAdvantage plan to provide, reimburse
 18 for, or provide coverage of a counseling or refer-
 19 ral service if the MedicareAdvantage organiza-
 20 tion offering the plan—

21 “(i) objects to the provision of such
 22 service on moral or religious grounds; and

23 “(ii) in the manner and through the
 24 written instrumentalities such
 25 MedicareAdvantage organization deems ap-

1 *appropriate, makes available information on*
 2 *its policies regarding such service to pro-*
 3 *spective enrollees before or during enroll-*
 4 *ment and to enrollees within 90 days after*
 5 *the date that the organization or plan*
 6 *adopts a change in policy regarding such a*
 7 *counseling or referral service.*

8 *“(C) CONSTRUCTION.—Nothing in subpara-*
 9 *graph (B) shall be construed to affect disclosure*
 10 *requirements under State law or under the Em-*
 11 *ployee Retirement Income Security Act of 1974.*

12 *“(D) HEALTH CARE PROFESSIONAL DE-*
 13 *FINED.—For purposes of this paragraph, the*
 14 *term ‘health care professional’ means a physi-*
 15 *cian (as defined in section 1861(r)) or other*
 16 *health care professional if coverage for the profes-*
 17 *sional’s services is provided under the*
 18 *MedicareAdvantage plan for the services of the*
 19 *professional. Such term includes a podiatrist,*
 20 *optometrist, chiropractor, psychologist, dentist,*
 21 *licensed pharmacist, physician assistant, phys-*
 22 *ical or occupational therapist and therapy as-*
 23 *stant, speech-language pathologist, audiologist,*
 24 *registered or licensed practical nurse (including*
 25 *nurse practitioner, clinical nurse specialist, cer-*

1 *tified registered nurse anesthetist, and certified*
 2 *nurse-midwife), licensed certified social worker,*
 3 *registered respiratory therapist, and certified res-*
 4 *piratory therapy technician.*

5 “(4) *LIMITATIONS ON PHYSICIAN INCENTIVE*
 6 *PLANS.—*

7 “(A) *IN GENERAL.—No MedicareAdvantage*
 8 *organization may operate any physician incen-*
 9 *tive plan (as defined in subparagraph (B)) un-*
 10 *less the following requirements are met:*

11 “(i) *No specific payment is made di-*
 12 *rectly or indirectly under the plan to a phy-*
 13 *sician or physician group as an inducement*
 14 *to reduce or limit medically necessary serv-*
 15 *ices provided with respect to a specific indi-*
 16 *vidual enrolled with the organization.*

17 “(ii) *If the plan places a physician or*
 18 *physician group at substantial financial*
 19 *risk (as determined by the Secretary) for*
 20 *services not provided by the physician or*
 21 *physician group, the organization—*

22 “(I) *provides stop-loss protection*
 23 *for the physician or group that is ade-*
 24 *quate and appropriate, based on stand-*
 25 *ards developed by the Secretary that*

1 *take into account the number of physi-*
 2 *cians placed at such substantial finan-*
 3 *cial risk in the group or under the*
 4 *plan and the number of individuals*
 5 *enrolled with the organization who re-*
 6 *ceive services from the physician or*
 7 *group; and*

8 *“(II) conducts periodic surveys of*
 9 *both individuals enrolled and individ-*
 10 *uals previously enrolled with the orga-*
 11 *nization to determine the degree of ac-*
 12 *cess of such individuals to services pro-*
 13 *vided by the organization and satisfac-*
 14 *tion with the quality of such services.*

15 *“(iii) The organization provides the*
 16 *Secretary with descriptive information re-*
 17 *garding the plan, sufficient to permit the*
 18 *Secretary to determine whether the plan is*
 19 *in compliance with the requirements of this*
 20 *subparagraph.*

21 *“(B) PHYSICIAN INCENTIVE PLAN DE-*
 22 *FINED.—In this paragraph, the term ‘physician*
 23 *incentive plan’ means any compensation ar-*
 24 *rangement between a MedicareAdvantage organi-*
 25 *zation and a physician or physician group that*

1 *may directly or indirectly have the effect of re-*
 2 *ducing or limiting services provided with respect*
 3 *to individuals enrolled with the organization*
 4 *under this part.*

5 “(5) *LIMITATION ON PROVIDER INDEMNIFICA-*
 6 *TION.—A MedicareAdvantage organization may not*
 7 *provide (directly or indirectly) for a health care pro-*
 8 *fessional, provider of services, or other entity pro-*
 9 *viding health care services (or group of such profes-*
 10 *sionals, providers, or entities) to indemnify the orga-*
 11 *nization against any liability resulting from a civil*
 12 *action brought for any damage caused to an enrollee*
 13 *with a MedicareAdvantage plan of the organization*
 14 *under this part by the organization’s denial of medi-*
 15 *cally necessary care.*

16 “(6) *SPECIAL RULES FOR MEDICAREADVANTAGE*
 17 *PRIVATE FEE-FOR-SERVICE PLANS.—For purposes of*
 18 *applying this part (including subsection (k)(1)) and*
 19 *section 1866(a)(1)(O), a hospital (or other provider of*
 20 *services), a physician or other health care profes-*
 21 *sional, or other entity furnishing health care services*
 22 *is treated as having an agreement or contract in effect*
 23 *with a MedicareAdvantage organization (with respect*
 24 *to an individual enrolled in a MedicareAdvantage*
 25 *private fee-for-service plan it offers), if—*

1 “(A) the provider, professional, or other en-
 2 tity furnishes services that are covered under the
 3 plan to such an enrollee; and

4 “(B) before providing such services, the pro-
 5 vider, professional, or other entity —

6 “(i) has been informed of the individ-
 7 ual’s enrollment under the plan; and

8 “(ii) either—

9 “(I) has been informed of the
 10 terms and conditions of payment for
 11 such services under the plan; or

12 “(II) is given a reasonable oppor-
 13 tunity to obtain information con-
 14 cerning such terms and conditions,
 15 in a manner reasonably designed to effect
 16 informed agreement by a provider.

17 The previous sentence shall only apply in the absence
 18 of an explicit agreement between such a provider, pro-
 19 fessional, or other entity and the MedicareAdvantage
 20 organization.

21 “(k) TREATMENT OF SERVICES FURNISHED BY CER-
 22 TAIN PROVIDERS.—

23 “(1) IN GENERAL.—Except as provided in para-
 24 graph (2), a physician or other entity (other than a
 25 provider of services) that does not have a contract es-

1 *tablishing payment amounts for services furnished to*
 2 *an individual enrolled under this part with a*
 3 *MedicareAdvantage organization described in section*
 4 *1851(a)(2)(A) shall accept as payment in full for cov-*
 5 *ered services under this title that are furnished to*
 6 *such an individual the amounts that the physician or*
 7 *other entity could collect if the individual were not so*
 8 *enrolled. Any penalty or other provision of law that*
 9 *applies to such a payment with respect to an indi-*
 10 *vidual entitled to benefits under this title (but not en-*
 11 *rolled with a MedicareAdvantage organization under*
 12 *this part) also applies with respect to an individual*
 13 *so enrolled.*

14 “(2) *APPLICATION TO MEDICAREADVANTAGE PRI-*
 15 *VATE FEE-FOR-SERVICE PLANS.—*

16 “(A) *BALANCE BILLING LIMITS UNDER*
 17 *MEDICAREADVANTAGE PRIVATE FEE-FOR-SERVICE*
 18 *PLANS IN CASE OF CONTRACT PROVIDERS.—*

19 “(i) *IN GENERAL.—In the case of an*
 20 *individual enrolled in a MedicareAdvantage*
 21 *private fee-for-service plan under this part,*
 22 *a physician, provider of services, or other*
 23 *entity that has a contract (including*
 24 *through the operation of subsection (j)(6))*
 25 *establishing a payment rate for services fur-*

1 nished to the enrollee shall accept as pay-
 2 ment in full for covered services under this
 3 title that are furnished to such an indi-
 4 vidual an amount not to exceed (including
 5 any deductibles, coinsurance, copayments,
 6 or balance billing otherwise permitted under
 7 the plan) an amount equal to 115 percent
 8 of such payment rate.

9 “(ii) *PROCEDURES TO ENFORCE LIM-*
 10 *ITS.—The MedicareAdvantage organization*
 11 *that offers such a plan shall establish proce-*
 12 *dures, similar to the procedures described in*
 13 *section 1848(g)(1)(A), in order to carry out*
 14 *clause (i).*

15 “(iii) *ASSURING ENFORCEMENT.—If*
 16 *the MedicareAdvantage organization fails to*
 17 *establish and enforce procedures required*
 18 *under clause (ii), the organization is subject*
 19 *to intermediate sanctions under section*
 20 *1857(g).*

21 “(B) *ENROLLEE LIABILITY FOR NONCON-*
 22 *TRACT PROVIDERS.—For provisions—*

23 “(i) *establishing a minimum payment*
 24 *rate in the case of noncontract providers*

1 *under a MedicareAdvantage private fee-for-*
 2 *service plan, see section 1852(a)(2); or*

3 “(ii) *limiting enrollee liability in the*
 4 *case of covered services furnished by such*
 5 *providers, see paragraph (1) and section*
 6 *1866(a)(1)(O).*

7 “(C) *INFORMATION ON BENEFICIARY LIABIL-*
 8 *ITY.—*

9 “(i) *IN GENERAL.—Each*
 10 *MedicareAdvantage organization that offers*
 11 *a MedicareAdvantage private fee-for-service*
 12 *plan shall provide that enrollees under the*
 13 *plan who are furnished services for which*
 14 *payment is sought under the plan are pro-*
 15 *vided an appropriate explanation of bene-*
 16 *fits (consistent with that provided under*
 17 *parts A, B, and D, and, if applicable,*
 18 *under medicare supplemental policies) that*
 19 *includes a clear statement of the amount of*
 20 *the enrollee’s liability (including any liabil-*
 21 *ity for balance billing consistent with this*
 22 *subsection) with respect to payments for*
 23 *such services.*

24 “(ii) *ADVANCE NOTICE BEFORE RE-*
 25 *CEIPT OF INPATIENT HOSPITAL SERVICES*

1 *AND CERTAIN OTHER SERVICES.—In addi-*
 2 *tion, such organization shall, in its terms*
 3 *and conditions of payments to hospitals for*
 4 *inpatient hospital services and for other*
 5 *services identified by the Secretary for*
 6 *which the amount of the balance billing*
 7 *under subparagraph (A) could be substan-*
 8 *tial, require the hospital to provide to the*
 9 *enrollee, before furnishing such services and*
 10 *if the hospital imposes balance billing under*
 11 *subparagraph (A)—*

12 *“(I) notice of the fact that balance*
 13 *billing is permitted under such sub-*
 14 *paragraph for such services; and*

15 *“(II) a good faith estimate of the*
 16 *likely amount of such balance billing*
 17 *(if any), with respect to such services,*
 18 *based upon the presenting condition of*
 19 *the enrollee.*

20 *“(l) RETURN TO HOME SKILLED NURSING FACILITIES*
 21 *FOR COVERED POST-HOSPITAL EXTENDED CARE SERV-*
 22 *ICES.—*

23 *“(1) ENSURING RETURN TO HOME SNF.—*

24 *“(A) IN GENERAL.—In providing coverage*
 25 *of post-hospital extended care services, a*

1 *MedicareAdvantage plan shall provide for such*
 2 *coverage through a home skilled nursing facility*
 3 *if the following conditions are met:*

4 “(i) *ENROLLEE ELECTION.*—*The en-*
 5 *rollee elects to receive such coverage through*
 6 *such facility.*

7 “(ii) *SNF AGREEMENT.*—*The facility*
 8 *has a contract with the MedicareAdvantage*
 9 *organization for the provision of such serv-*
 10 *ices, or the facility agrees to accept substan-*
 11 *tially similar payment under the same*
 12 *terms and conditions that apply to simi-*
 13 *larly situated skilled nursing facilities that*
 14 *are under contract with the*
 15 *MedicareAdvantage organization for the*
 16 *provision of such services and through*
 17 *which the enrollee would otherwise receive*
 18 *such services.*

19 “(B) *MANNER OF PAYMENT TO HOME*
 20 *SNF.*—*The organization shall provide payment*
 21 *to the home skilled nursing facility consistent*
 22 *with the contract or the agreement described in*
 23 *subparagraph (A)(ii), as the case may be.*

24 “(2) *NO LESS FAVORABLE COVERAGE.*—*The cov-*
 25 *erage provided under paragraph (1) (including scope*

1 *of services, cost-sharing, and other criteria of cov-*
 2 *erage) shall be no less favorable to the enrollee than*
 3 *the coverage that would be provided to the enrollee*
 4 *with respect to a skilled nursing facility the post-hos-*
 5 *pital extended care services of which are otherwise*
 6 *covered under the MedicareAdvantage plan.*

7 “(3) *RULE OF CONSTRUCTION.*—*Nothing in this*
 8 *subsection shall be construed to do the following:*

9 “(A) *To require coverage through a skilled*
 10 *nursing facility that is not otherwise qualified to*
 11 *provide benefits under part A for medicare bene-*
 12 *ficiaries not enrolled in a MedicareAdvantage*
 13 *plan.*

14 “(B) *To prevent a skilled nursing facility*
 15 *from refusing to accept, or imposing conditions*
 16 *upon the acceptance of, an enrollee for the receipt*
 17 *of post-hospital extended care services.*

18 “(4) *DEFINITIONS.*—*In this subsection:*

19 “(A) *HOME SKILLED NURSING FACILITY.*—
 20 *The term ‘home skilled nursing facility’ means,*
 21 *with respect to an enrollee who is entitled to re-*
 22 *ceive post-hospital extended care services under a*
 23 *MedicareAdvantage plan, any of the following*
 24 *skilled nursing facilities:*

1 “(i) *SNF RESIDENCE AT TIME OF AD-*
 2 *MISSION.—The skilled nursing facility in*
 3 *which the enrollee resided at the time of ad-*
 4 *mission to the hospital preceding the receipt*
 5 *of such post-hospital extended care services.*

6 “(ii) *SNF IN CONTINUING CARE RE-*
 7 *TIREMENT COMMUNITY.—A skilled nursing*
 8 *facility that is providing such services*
 9 *through a continuing care retirement com-*
 10 *munity (as defined in subparagraph (B))*
 11 *which provided residence to the enrollee at*
 12 *the time of such admission.*

13 “(iii) *SNF RESIDENCE OF SPOUSE AT*
 14 *TIME OF DISCHARGE.—The skilled nursing*
 15 *facility in which the spouse of the enrollee*
 16 *is residing at the time of discharge from*
 17 *such hospital.*

18 “(B) *CONTINUING CARE RETIREMENT COM-*
 19 *MUNITY.—The term ‘continuing care retirement*
 20 *community’ means, with respect to an enrollee in*
 21 *a MedicareAdvantage plan, an arrangement*
 22 *under which housing and health-related services*
 23 *are provided (or arranged) through an organiza-*
 24 *tion for the enrollee under an agreement that is*

1 *effective for the life of the enrollee or for a speci-*
 2 *fied period.”.*

3 **SEC. 203. PAYMENTS TO MEDICAREADVANTAGE ORGANIZA-**
 4 **TIONS.**

5 *Section 1853 (42 U.S.C. 1395w–23) is amended to*
 6 *read as follows:*

7 “PAYMENTS TO MEDICAREADVANTAGE ORGANIZATIONS

8 “SEC. 1853. (a) PAYMENTS TO ORGANIZATIONS.—

9 “(1) MONTHLY PAYMENTS.—

10 “(A) IN GENERAL.—Under a contract under
 11 *section 1857 and subject to subsections (f), (h),*
 12 *and (j) and section 1859(e)(4), the Secretary*
 13 *shall make, to each MedicareAdvantage organiza-*
 14 *tion, with respect to coverage of an individual*
 15 *for a month under this part in a*
 16 *MedicareAdvantage payment area, separate*
 17 *monthly payments with respect to—*

18 “(i) *benefits under the original medi-*
 19 *care fee-for-service program under parts A*
 20 *and B in accordance with subsection (d);*
 21 *and*

22 “(ii) *benefits under the voluntary pre-*
 23 *scription drug program under part D in*
 24 *accordance with section 1858A and the*
 25 *other provisions of this part.*

1 “(B) *SPECIAL RULE FOR END-STAGE RENAL*
2 *DISEASE.—The Secretary shall establish separate*
3 *rates of payment to a MedicareAdvantage orga-*
4 *nization with respect to classes of individuals de-*
5 *termined to have end-stage renal disease and en-*
6 *rolled in a MedicareAdvantage plan of the orga-*
7 *nization. Such rates of payment shall be actuari-*
8 *ally equivalent to rates paid to other enrollees in*
9 *the MedicareAdvantage payment area (or such*
10 *other area as specified by the Secretary). In ac-*
11 *cordance with regulations, the Secretary shall*
12 *provide for the application of the seventh sen-*
13 *tence of section 1881(b)(7) to payments under*
14 *this section covering the provision of renal dialy-*
15 *sis treatment in the same manner as such sen-*
16 *tence applies to composite rate payments de-*
17 *scribed in such sentence. In establishing such*
18 *rates, the Secretary shall provide for appropriate*
19 *adjustments to increase each rate to reflect the*
20 *demonstration rate (including the risk adjust-*
21 *ment methodology associated with such rate) of*
22 *the social health maintenance organization end-*
23 *stage renal disease capitation demonstrations*
24 *(established by section 2355 of the Deficit Reduc-*
25 *tion Act of 1984, as amended by section 13567(b)*

1 *of the Omnibus Budget Reconciliation Act of*
 2 *1993), and shall compute such rates by taking*
 3 *into account such factors as renal treatment mo-*
 4 *dalidity, age, and the underlying cause of the end-*
 5 *stage renal disease.*

6 “(2) *ADJUSTMENT TO REFLECT NUMBER OF EN-*
 7 *ROLLEES.—*

8 “(A) *IN GENERAL.—The amount of pay-*
 9 *ment under this subsection may be retroactively*
 10 *adjusted to take into account any difference be-*
 11 *tween the actual number of individuals enrolled*
 12 *with an organization under this part and the*
 13 *number of such individuals estimated to be so*
 14 *enrolled in determining the amount of the ad-*
 15 *vance payment.*

16 “(B) *SPECIAL RULE FOR CERTAIN ENROLL-*
 17 *EES.—*

18 “(i) *IN GENERAL.—Subject to clause*
 19 *(ii), the Secretary may make retroactive ad-*
 20 *justments under subparagraph (A) to take*
 21 *into account individuals enrolled during the*
 22 *period beginning on the date on which the*
 23 *individual enrolls with a*
 24 *MedicareAdvantage organization under a*
 25 *plan operated, sponsored, or contributed to*

1 by the individual’s employer or former em-
 2 ployer (or the employer or former employer
 3 of the individual’s spouse) and ending on
 4 the date on which the individual is enrolled
 5 in the organization under this part, except
 6 that for purposes of making such retroactive
 7 adjustments under this subparagraph, such
 8 period may not exceed 90 days.

9 “(ii) *EXCEPTION.*—No adjustment may
 10 be made under clause (i) with respect to
 11 any individual who does not certify that the
 12 organization provided the individual with
 13 the disclosure statement described in section
 14 1852(c) at the time the individual enrolled
 15 with the organization.

16 “(C) *EQUALIZATION OF FEDERAL CON-*
 17 *TRIBUTION.*—In applying subparagraph (A), the
 18 Secretary shall ensure that the payment to the
 19 MedicareAdvantage organization for each indi-
 20 vidual enrolled with the organization shall equal
 21 the MedicareAdvantage benchmark amount for
 22 the payment area in which that individual re-
 23 sides (as determined under paragraph (4)), as
 24 adjusted—

1 “(i) by multiplying the benchmark
2 amount for that payment area by the ratio
3 of—

4 “(I) the payment amount deter-
5 mined under subsection (d)(4); to

6 “(II) the weighted service area
7 benchmark amount determined under
8 subsection (d)(2); and

9 “(ii) using such risk adjustment factor
10 as specified by the Secretary under sub-
11 section (b)(1)(B).

12 “(3) COMPREHENSIVE RISK ADJUSTMENT METH-
13 ODOLOGY.—

14 “(A) APPLICATION OF METHODOLOGY.—The
15 Secretary shall apply the comprehensive risk ad-
16 justment methodology described in subparagraph
17 (B) to 100 percent of the amount of payments to
18 plans under subsection (d)(4)(B).

19 “(B) COMPREHENSIVE RISK ADJUSTMENT
20 METHODOLOGY DESCRIBED.—The comprehensive
21 risk adjustment methodology described in this
22 subparagraph is the risk adjustment methodology
23 that would apply with respect to
24 MedicareAdvantage plans offered by
25 MedicareAdvantage organizations in 2005, ex-

cept that if such methodology does not apply to groups of beneficiaries who are aged or disabled and groups of beneficiaries who have end-stage renal disease, the Secretary shall revise such methodology to apply to such groups.

“(C) *UNIFORM APPLICATION TO ALL TYPES OF PLANS.*—Subject to section 1859(e)(4), the comprehensive risk adjustment methodology established under this paragraph shall be applied uniformly without regard to the type of plan.

“(D) *DATA COLLECTION.*—In order to carry out this paragraph, the Secretary shall require MedicareAdvantage organizations to submit such data and other information as the Secretary deems necessary.

“(E) *IMPROVEMENT OF PAYMENT ACCURACY.*—Notwithstanding any other provision of this paragraph, the Secretary may revise the comprehensive risk adjustment methodology described in subparagraph (B) from time to time to improve payment accuracy.

“(4) *ANNUAL CALCULATION OF BENCHMARK AMOUNTS.*—For each year, the Secretary shall calculate a benchmark amount for each MedicareAdvantage payment area for each month for

1 *such year with respect to coverage of the benefits*
 2 *available under the original medicare fee-for-service*
 3 *program option equal to the greater of the following*
 4 *amounts (adjusted as appropriate for the application*
 5 *of the risk adjustment methodology under paragraph*
 6 *(3)):*

7 “(A) *MINIMUM AMOUNT.*—^{1/12} *of the annual*
 8 *Medicare+Choice capitation rate determined*
 9 *under subsection (c)(1)(B) for the payment area*
 10 *for the year.*

11 “(B) *LOCAL FEE-FOR-SERVICE RATE.*—*The*
 12 *local fee-for-service rate for such area for the*
 13 *year (as calculated under paragraph (5)).*

14 “(5) *ANNUAL CALCULATION OF LOCAL FEE-FOR-*
 15 *SERVICE RATES.*—

16 “(A) *IN GENERAL.*—*Subject to subpara-*
 17 *graph (B), the term ‘local fee-for-service rate’*
 18 *means the amount of payment for a month in a*
 19 *MedicareAdvantage payment area for benefits*
 20 *under this title and associated claims processing*
 21 *costs for an individual who has elected to receive*
 22 *benefits under the original medicare fee-for-serv-*
 23 *ice program option and not enrolled in a*
 24 *MedicareAdvantage plan under this part. The*
 25 *Secretary shall annually calculate such amount*

1 *in a manner similar to the manner in which the*
 2 *Secretary calculated the adjusted average per*
 3 *capita cost under section 1876.*

4 “(B) *REMOVAL OF MEDICAL EDUCATION*
 5 *COSTS FROM CALCULATION OF LOCAL FEE-FOR-*
 6 *SERVICE RATE.—*

7 “(i) *IN GENERAL.—In calculating the*
 8 *local fee-for-service rate under subparagraph*
 9 *(A) for a year, the amount of payment de-*
 10 *scribed in such subparagraph shall be ad-*
 11 *justed to exclude from such payment the*
 12 *payment adjustments described in clause*
 13 *(ii).*

14 “(ii) *PAYMENT ADJUSTMENTS DE-*
 15 *SCRIBED.—*

16 “(I) *IN GENERAL.—Subject to*
 17 *subclause (II), the payment adjust-*
 18 *ments described in this subparagraph*
 19 *are payment adjustments which the*
 20 *Secretary estimates are payable during*
 21 *the year—*

22 “(aa) *for the indirect costs of*
 23 *medical education under section*
 24 *1886(d)(5)(B); and*

1 “(bb) for direct graduate
2 medical education costs under sec-
3 tion 1886(h).

4 “(II) TREATMENT OF PAYMENTS
5 COVERED UNDER STATE HOSPITAL RE-
6 IMBURSEMENT SYSTEM.—To the extent
7 that the Secretary estimates that the
8 amount of the local fee-for-service rates
9 reflects payments to hospitals reim-
10 bursed under section 1814(b)(3), the
11 Secretary shall estimate a payment ad-
12 justment that is comparable to the
13 payment adjustment that would have
14 been made under clause (i) if the hos-
15 pitals had not been reimbursed under
16 such section.

17 “(b) ANNUAL ANNOUNCEMENT OF PAYMENT FAC-
18 TORS.—

19 “(1) ANNUAL ANNOUNCEMENT.—Beginning in
20 2005, at the same time as the Secretary publishes the
21 risk adjusters under section 1860D–11, the Secretary
22 shall annually announce (in a manner intended to
23 provide notice to interested parties) the following pay-
24 ment factors:

1 “(A) The benchmark amount for each
2 MedicareAdvantage payment area (as calculated
3 under subsection (a)(4)) for the year.

4 “(B) The factors to be used for adjusting
5 payments under the comprehensive risk adjust-
6 ment methodology described in subsection
7 (a)(3)(B) with respect to each
8 MedicareAdvantage payment area for the year.

9 “(2) ADVANCE NOTICE OF METHODOLOGICAL
10 CHANGES.—At least 45 days before making the an-
11 nouncement under paragraph (1) for a year, the Sec-
12 retary shall—

13 “(A) provide for notice to
14 MedicareAdvantage organizations of proposed
15 changes to be made in the methodology from the
16 methodology and assumptions used in the pre-
17 vious announcement; and

18 “(B) provide such organizations with an
19 opportunity to comment on such proposed
20 changes.

21 “(3) EXPLANATION OF ASSUMPTIONS.—In each
22 announcement made under paragraph (1), the Sec-
23 retary shall include an explanation of the assump-
24 tions and changes in methodology used in the an-
25 nouncement in sufficient detail so that

1 *MedicareAdvantage organizations can compute each*
 2 *payment factor described in paragraph (1).*

3 “(c) *CALCULATION OF ANNUAL MEDICARE+CHOICE*
 4 *CAPITATION RATES.—*

5 “(1) *IN GENERAL.—For purposes of making pay-*
 6 *ments under this part for years before 2006 and for*
 7 *purposes of calculating the annual Medicare+Choice*
 8 *capitation rates under paragraph (7) beginning with*
 9 *such year, subject to paragraph (6)(C), each annual*
 10 *Medicare+Choice capitation rate, for a*
 11 *Medicare+Choice payment area before 2006 or a*
 12 *MedicareAdvantage payment area beginning with*
 13 *such year for a contract year consisting of a calendar*
 14 *year, is equal to the largest of the amounts specified*
 15 *in the following subparagraph (A), (B), or (C):*

16 “(A) *BLENDED CAPITATION RATE.—The*
 17 *sum of—*

18 “(i) *the area-specific percentage (as*
 19 *specified under paragraph (2) for the year)*
 20 *of the annual area-specific*
 21 *Medicare+Choice capitation rate for the*
 22 *MedicareAdvantage payment area, as deter-*
 23 *mined under paragraph (3) for the year;*
 24 *and*

1 “(ii) the national percentage (as speci-
 2 fied under paragraph (2) for the year) of
 3 the input-price-adjusted annual national
 4 Medicare+Choice capitation rate, as deter-
 5 mined under paragraph (4) for the year,
 6 multiplied by the budget neutrality adjustment
 7 factor determined under paragraph (5).

8 “(B) MINIMUM AMOUNT.—12 multiplied by
 9 the following amount:

10 “(i) For 1998, \$367 (but not to exceed,
 11 in the case of an area outside the 50 States
 12 and the District of Columbia, 150 percent of
 13 the annual per capita rate of payment for
 14 1997 determined under section
 15 1876(a)(1)(C) for the area).

16 “(ii) For 1999 and 2000, the min-
 17 imum amount determined under clause (i)
 18 or this clause, respectively, for the preceding
 19 year, increased by the national per capita
 20 Medicare+Choice growth percentage de-
 21 scribed in paragraph (6)(A) applicable to
 22 1999 or 2000, respectively.

23 “(iii)(I) Subject to subclause (II), for
 24 2001, for any area in a Metropolitan Sta-
 25 tistical Area with a population of more

1 *than 250,000, \$525, and for any other area*
 2 *\$475.*

3 *“(II) In the case of an area outside the*
 4 *50 States and the District of Columbia, the*
 5 *amount specified in this clause shall not ex-*
 6 *ceed 120 percent of the amount determined*
 7 *under clause (ii) for such area for 2000.*

8 *“(iv) For 2002 through 2013, the min-*
 9 *imum amount specified in this clause (or*
 10 *clause (iii)) for the preceding year increased*
 11 *by the national per capita*
 12 *Medicare+Choice growth percentage, de-*
 13 *scribed in paragraph (6)(A) for that suc-*
 14 *ceeding year.*

15 *“(v) For 2014 and each succeeding*
 16 *year, the minimum amount specified in this*
 17 *clause (or clause (iv)) for the preceding year*
 18 *increased by the percentage increase in the*
 19 *Consumer Price Index for all urban con-*
 20 *sumers (U.S. urban average) for the 12-*
 21 *month period ending with June of the pre-*
 22 *vious year.*

23 *“(C) MINIMUM PERCENTAGE INCREASE.—*

24 *“(i) For 1998, 102 percent of the an-*
 25 *nuual per capita rate of payment for 1997*

1 *determined under section 1876(a)(1)(C) for*
 2 *the Medicare+Choice payment area.*

3 “(ii) *For 1999 and 2000, 102 percent*
 4 *of the annual Medicare+Choice capitation*
 5 *rate under this paragraph for the area for*
 6 *the previous year.*

7 “(iii) *For 2001, 103 percent of the an-*
 8 *nual Medicare+Choice capitation rate*
 9 *under this paragraph for the area for 2000.*

10 “(iv) *For 2002, 2003, and 2004, 102*
 11 *percent of the annual Medicare+Choice*
 12 *capitation rate under this paragraph for*
 13 *the area for the previous year.*

14 “(v) *For 2005, 103 percent of the an-*
 15 *nual Medicare+Choice capitation rate*
 16 *under this paragraph for the area for 2003.*

17 “(vi) *For 2006 and each succeeding*
 18 *year, 102 percent of the annual*
 19 *Medicare+Choice capitation rate under this*
 20 *paragraph for the area for the previous*
 21 *year, except that such rate shall be deter-*
 22 *mined by substituting ‘102’ for ‘103’ in*
 23 *clause (v).*

24 “(2) *AREA-SPECIFIC AND NATIONAL PERCENT-*
 25 *AGES.—For purposes of paragraph (1)(A)—*

1 “(A) for 1998, the ‘area-specific percentage’
 2 is 90 percent and the ‘national percentage’ is 10
 3 percent;

4 “(B) for 1999, the ‘area-specific percentage’
 5 is 82 percent and the ‘national percentage’ is 18
 6 percent;

7 “(C) for 2000, the ‘area-specific percentage’
 8 is 74 percent and the ‘national percentage’ is 26
 9 percent;

10 “(D) for 2001, the ‘area-specific percentage’
 11 is 66 percent and the ‘national percentage’ is 34
 12 percent;

13 “(E) for 2002, the ‘area-specific percentage’
 14 is 58 percent and the ‘national percentage’ is 42
 15 percent; and

16 “(F) for a year after 2002, the ‘area-specific
 17 percentage’ is 50 percent and the ‘national per-
 18 centage’ is 50 percent.

19 “(3) ANNUAL AREA-SPECIFIC MEDICARE+CHOICE
 20 CAPITATION RATE.—

21 “(A) IN GENERAL.—For purposes of para-
 22 graph (1)(A), subject to subparagraph (B), the
 23 annual area-specific Medicare+Choice capita-
 24 tion rate for a Medicare+Choice payment
 25 area—

1 “(i) for 1998 is, subject to subpara-
 2 graph (D), the annual per capita rate of
 3 payment for 1997 determined under section
 4 1876(a)(1)(C) for the area, increased by the
 5 national per capita Medicare+Choice
 6 growth percentage for 1998 (described in
 7 paragraph (6)(A)); or

8 “(ii) for a subsequent year is the an-
 9 nual area-specific Medicare+Choice capita-
 10 tion rate for the previous year determined
 11 under this paragraph for the area, increased
 12 by the national per capita
 13 Medicare+Choice growth percentage for
 14 such subsequent year.

15 “(B) REMOVAL OF MEDICAL EDUCATION
 16 FROM CALCULATION OF ADJUSTED AVERAGE PER
 17 CAPITA COST.—

18 “(i) IN GENERAL.—In determining the
 19 area-specific Medicare+Choice capitation
 20 rate under subparagraph (A) for a year (be-
 21 ginning with 1998), the annual per capita
 22 rate of payment for 1997 determined under
 23 section 1876(a)(1)(C) shall be adjusted to
 24 exclude from the rate the applicable percent

(specified in clause (ii)) of the payment adjustments described in subparagraph (C).

“(ii) *APPLICABLE PERCENT.*—For purposes of clause (i), the applicable percent for—

“(I) 1998 is 20 percent;

“(II) 1999 is 40 percent;

“(III) 2000 is 60 percent;

“(IV) 2001 is 80 percent; and

“(V) a succeeding year is 100 percent.

“(C) *PAYMENT ADJUSTMENT.*—

“(i) *IN GENERAL.*—Subject to clause (ii), the payment adjustments described in this subparagraph are payment adjustments which the Secretary estimates were payable during 1997—

“(I) for the indirect costs of medical education under section 1886(d)(5)(B); and

“(II) for direct graduate medical education costs under section 1886(h).

“(ii) *TREATMENT OF PAYMENTS COVERED UNDER STATE HOSPITAL REIMBURSEMENT SYSTEM.*—To the extent that the Sec-

retary estimates that an annual per capita rate of payment for 1997 described in clause (i) reflects payments to hospitals reimbursed under section 1814(b)(3), the Secretary shall estimate a payment adjustment that is comparable to the payment adjustment that would have been made under clause (i) if the hospitals had not been reimbursed under such section.

“(D) *TREATMENT OF AREAS WITH HIGHLY VARIABLE PAYMENT RATES.*—In the case of a Medicare+Choice payment area for which the annual per capita rate of payment determined under section 1876(a)(1)(C) for 1997 varies by more than 20 percent from such rate for 1996, for purposes of this subsection the Secretary may substitute for such rate for 1997 a rate that is more representative of the costs of the enrollees in the area.

“(4) *INPUT-PRICE-ADJUSTED ANNUAL NATIONAL MEDICARE+CHOICE CAPITATION RATE.*—

“(A) *IN GENERAL.*—For purposes of paragraph (1)(A), the input-price-adjusted annual national Medicare+Choice capitation rate for a Medicare+Choice payment area for a year is

1 *equal to the sum, for all the types of medicare*
 2 *services (as classified by the Secretary), of the*
 3 *product (for each such type of service) of—*

4 “(i) *the national standardized annual*
 5 *Medicare+Choice capitation rate (deter-*
 6 *mined under subparagraph (B)) for the*
 7 *year;*

8 “(ii) *the proportion of such rate for the*
 9 *year which is attributable to such type of*
 10 *services; and*

11 “(iii) *an index that reflects (for that*
 12 *year and that type of services) the relative*
 13 *input price of such services in the area com-*
 14 *pared to the national average input price of*
 15 *such services.*

16 *In applying clause (iii), the Secretary may, sub-*
 17 *ject to subparagraph (C), apply those indices*
 18 *under this title that are used in applying (or up-*
 19 *dating) national payment rates for specific areas*
 20 *and localities.*

21 “(B) *NATIONAL STANDARDIZED ANNUAL*
 22 *MEDICARE+CHOICE CAPITATION RATE.—In sub-*
 23 *paragraph (A)(i), the ‘national standardized an-*
 24 *nual Medicare+Choice capitation rate’ for a*
 25 *year is equal to—*

1 “(i) the sum (for all Medicare+Choice
2 payment areas) of the product of—

3 “(I) the annual area-specific
4 Medicare+Choice capitation rate for
5 that year for the area under paragraph
6 (3); and

7 “(II) the average number of medi-
8 care beneficiaries residing in that area
9 in the year, multiplied by the average
10 of the risk factor weights used to adjust
11 payments under subsection (a)(1)(A)
12 for such beneficiaries in such area; di-
13 vided by

14 “(ii) the sum of the products described
15 in clause (i)(II) for all areas for that year.

16 “(5) PAYMENT ADJUSTMENT BUDGET NEU-
17 TRALITY FACTOR.—For purposes of paragraph (1)(A),
18 for each year, the Secretary shall determine a budget
19 neutrality adjustment factor so that the aggregate of
20 the payments under this part (other than those attrib-
21 utable to subsections (a)(3)(C)(iii) and (i)) shall
22 equal the aggregate payments that would have been
23 made under this part if payment were based entirely
24 on area-specific capitation rates.

1 “(6) *NATIONAL PER CAPITA MEDICARE+CHOICE*
2 *GROWTH PERCENTAGE DEFINED.*—

3 “(A) *IN GENERAL.*—*In this part, the ‘na-*
4 *tional per capita Medicare+Choice growth per-*
5 *centage’ for a year is the percentage determined*
6 *by the Secretary, by March 1st before the begin-*
7 *ning of the year involved, to reflect the Sec-*
8 *retary’s estimate of the projected per capita rate*
9 *of growth in expenditures under this title for an*
10 *individual entitled to (or enrolled for) benefits*
11 *under part A and enrolled under part B, reduced*
12 *by the number of percentage points specified in*
13 *subparagraph (B) for the year. Separate deter-*
14 *minations may be made for aged enrollees, dis-*
15 *abled enrollees, and enrollees with end-stage*
16 *renal disease.*

17 “(B) *ADJUSTMENT.*—*The number of per-*
18 *centage points specified in this subparagraph*
19 *is—*

20 “(i) *for 1998, 0.8 percentage points;*

21 “(ii) *for 1999, 0.5 percentage points;*

22 “(iii) *for 2000, 0.5 percentage points;*

23 “(iv) *for 2001, 0.5 percentage points;*

24 “(v) *for 2002, 0.3 percentage points;*

25 *and*

1 “(vi) for a year after 2002, 0 percent-
2 age points.

3 “(C) *ADJUSTMENT FOR OVER OR UNDER*
4 *PROJECTION OF NATIONAL PER CAPITA*
5 *MEDICARE+CHOICE GROWTH PERCENTAGE.*—Be-
6 ginning with rates calculated for 1999, before
7 computing rates for a year as described in para-
8 graph (1), the Secretary shall adjust all area-
9 specific and national Medicare+Choice capita-
10 tion rates (and beginning in 2000, the minimum
11 amount) for the previous year for the differences
12 between the projections of the national per capita
13 Medicare+Choice growth percentage for that
14 year and previous years and the current estimate
15 of such percentage for such years.

16 “(7) *TRANSITION TO MEDICAREADVANTAGE COM-*
17 *PETITION.*—

18 “(A) *IN GENERAL.*—For each year (begin-
19 ning with 2006) payments to MedicareAdvantage
20 plans shall not be computed under this sub-
21 section, but instead shall be based on the pay-
22 ment amount determined under subsection (d).

23 “(B) *CONTINUED CALCULATION OF CAPITA-*
24 *TION RATES.*—For each year (beginning with
25 2006) the Secretary shall calculate and publish

1 *the annual Medicare+Choice capitation rates*
 2 *under this subsection and shall use the annual*
 3 *Medicare+Choice capitation rate determined*
 4 *under subsection (c)(1) for purposes of deter-*
 5 *mining the benchmark amount under subsection*
 6 *(a)(4).*

7 “(d) *SECRETARY’S DETERMINATION OF PAYMENT*
 8 *AMOUNT.—*

9 “(1) *REVIEW OF PLAN BIDS.—The Secretary*
 10 *shall review each plan bid submitted under section*
 11 *1854(a) for the coverage of benefits under the original*
 12 *medicare fee-for-service program option to ensure that*
 13 *such bids are consistent with the requirements under*
 14 *this part an are based on the assumptions described*
 15 *in section 1854(a)(2)(A)(iii).*

16 “(2) *DETERMINATION OF WEIGHTED SERVICE*
 17 *AREA BENCHMARK AMOUNTS.—The Secretary shall*
 18 *calculate a weighted service area benchmark amount*
 19 *for the benefits under the original medicare fee-for-*
 20 *service program option for each plan equal to the*
 21 *weighted average of the benchmark amounts for bene-*
 22 *fits under such original medicare fee-for-service pro-*
 23 *gram option for the payment areas included in the*
 24 *service area of the plan using the assumptions de-*
 25 *scribed in section 1854(a)(2)(A)(iii).*

1 “(3) *COMPARISON TO BENCHMARK.*—*The Sec-*
 2 *retary shall determine the difference between each*
 3 *plan bid (as adjusted under paragraph (1)) and the*
 4 *weighted service area benchmark amount (as deter-*
 5 *mined under paragraph (2)) for purposes of*
 6 *determining—*

7 “(A) *the payment amount under paragraph*
 8 *(4); and*

9 “(B) *the additional benefits required and*
 10 *MedicareAdvantage monthly basic beneficiary*
 11 *premiums.*

12 “(4) *DETERMINATION OF PAYMENT AMOUNT FOR*
 13 *ORIGINAL MEDICARE FEE-FOR-SERVICE BENEFITS.—*

14 “(A) *IN GENERAL.*—*Subject to subpara-*
 15 *graph (B), the Secretary shall determine the*
 16 *payment amount for MedicareAdvantage plans*
 17 *for the benefits under the original medicare fee-*
 18 *for-service program option as follows:*

19 “(i) *BIDS THAT EQUAL OR EXCEED*
 20 *THE BENCHMARK.*—*In the case of a plan*
 21 *bid that equals or exceeds the weighted serv-*
 22 *ice area benchmark amount, the amount of*
 23 *each monthly payment to a*
 24 *MedicareAdvantage organization with re-*
 25 *spect to each individual enrolled in a plan*

1 *shall be the weighted service area benchmark*
 2 *amount.*

3 “(ii) *BIDS BELOW THE BENCHMARK.—*
 4 *In the case of a plan bid that is less than*
 5 *the weighted service area benchmark*
 6 *amount, the amount of each monthly pay-*
 7 *ment to a MedicareAdvantage organization*
 8 *with respect to each individual enrolled in*
 9 *a plan shall be the weighted service area*
 10 *benchmark amount reduced by the amount*
 11 *of any premium reduction elected by the*
 12 *plan under section 1854(d)(1)(A)(i).*

13 “(B) *APPLICATION OF COMPREHENSIVE*
 14 *RISK ADJUSTMENT METHODOLOGY.—The Sec-*
 15 *retary shall adjust the amounts determined*
 16 *under subparagraph (A) using the comprehensive*
 17 *risk adjustment methodology applicable under*
 18 *subsection (a)(3).*

19 “(6) *ADJUSTMENT FOR NATIONAL COVERAGE DE-*
 20 *TERMINATIONS AND LEGISLATIVE CHANGES IN BENE-*
 21 *FITS.—If the Secretary makes a determination with*
 22 *respect to coverage under this title or there is a*
 23 *change in benefits required to be provided under this*
 24 *part that the Secretary projects will result in a sig-*
 25 *nificant increase in the costs to MedicareAdvantage*

1 *organizations of providing benefits under contracts*
 2 *under this part (for periods after any period de-*
 3 *scribed in section 1852(a)(5)), the Secretary shall ap-*
 4 *propriately adjust the benchmark amounts or pay-*
 5 *ment amounts (as determined by the Secretary). Such*
 6 *projection and adjustment shall be based on an anal-*
 7 *ysis by the Secretary of the actuarial costs associated*
 8 *with the new benefits.*

9 “(7) *BENEFITS UNDER THE ORIGINAL MEDICARE*
 10 *FEE-FOR-SERVICE PROGRAM OPTION DEFINED.—For*
 11 *purposes of this part, the term ‘benefits under the*
 12 *original medicare fee-for-service program option’*
 13 *means those items and services (other than hospice*
 14 *care) for which benefits are available under parts A*
 15 *and B to individuals entitled to, or enrolled for, bene-*
 16 *fits under part A and enrolled under part B, with*
 17 *cost-sharing for those services as required under parts*
 18 *A and B or an actuarially equivalent level of cost-*
 19 *sharing as determined in this part.*

20 “(e) *MEDICAREADVANTAGE PAYMENT AREA DE-*
 21 *FINED.—*

22 “(1) *IN GENERAL.—In this part, except as pro-*
 23 *vided in paragraph (3), the term ‘MedicareAdvantage*
 24 *payment area’ means a county, or equivalent area*
 25 *specified by the Secretary.*

1 “(2) *RULE FOR ESRD BENEFICIARIES.*—*In the*
 2 *case of individuals who are determined to have end*
 3 *stage renal disease, the MedicareAdvantage payment*
 4 *area shall be a State or such other payment area as*
 5 *the Secretary specifies.*

6 “(3) *GEOGRAPHIC ADJUSTMENT.*—

7 “(A) *IN GENERAL.*—*Upon written request of*
 8 *the chief executive officer of a State for a con-*
 9 *tract year (beginning after 2005) made by not*
 10 *later than February 1 of the previous year, the*
 11 *Secretary shall make a geographic adjustment to*
 12 *a MedicareAdvantage payment area in the State*
 13 *otherwise determined under paragraph (1)—*

14 “(i) *to a single statewide*
 15 *MedicareAdvantage payment area;*

16 “(ii) *to the metropolitan based system*
 17 *described in subparagraph (C); or*

18 “(iii) *to consolidating into a single*
 19 *MedicareAdvantage payment area non-*
 20 *contiguous counties (or equivalent areas de-*
 21 *scribed in paragraph (1)) within a State.*

22 *Such adjustment shall be effective for payments*
 23 *for months beginning with January of the year*
 24 *following the year in which the request is re-*
 25 *ceived.*

“(B) *BUDGET NEUTRALITY ADJUSTMENT.*—

In the case of a State requesting an adjustment under this paragraph, the Secretary shall initially (and annually thereafter) adjust the payment rates otherwise established under this section for MedicareAdvantage payment areas in the State in a manner so that the aggregate of the payments under this section in the State shall not exceed the aggregate payments that would have been made under this section for MedicareAdvantage payment areas in the State in the absence of the adjustment under this paragraph.

“(C) *METROPOLITAN BASED SYSTEM.*—*The metropolitan based system described in this subparagraph is one in which—*

“(i) all the portions of each metropolitan statistical area in the State or in the case of a consolidated metropolitan statistical area, all of the portions of each primary metropolitan statistical area within the consolidated area within the State, are treated as a single MedicareAdvantage payment area; and

1 “(ii) *all areas in the State that do not*
 2 *fall within a metropolitan statistical area*
 3 *are treated as a single MedicareAdvantage*
 4 *payment area.*

5 “(D) *AREAS.*—*In subparagraph (C), the*
 6 *terms ‘metropolitan statistical area’, ‘consoli-*
 7 *dated metropolitan statistical area’, and ‘pri-*
 8 *mary metropolitan statistical area’ mean any*
 9 *area designated as such by the Secretary of Com-*
 10 *merce.*

11 “(f) *SPECIAL RULES FOR INDIVIDUALS ELECTING*
 12 *MSA PLANS.*—

13 “(1) *IN GENERAL.*—*If the amount of the*
 14 *MedicareAdvantage monthly MSA premium (as de-*
 15 *fined in section 1854(b)(2)(D)) for an MSA plan for*
 16 *a year is less than $\frac{1}{12}$ of the annual*
 17 *Medicare+Choice capitation rate applied under this*
 18 *section for the area and year involved, the Secretary*
 19 *shall deposit an amount equal to 100 percent of such*
 20 *difference in a MedicareAdvantage MSA established*
 21 *(and, if applicable, designated) by the individual*
 22 *under paragraph (2).*

23 “(2) *ESTABLISHMENT AND DESIGNATION OF*
 24 *MEDICAREADVANTAGE MEDICAL SAVINGS ACCOUNT AS*
 25 *REQUIREMENT FOR PAYMENT OF CONTRIBUTION.*—*In*

1 *the case of an individual who has elected coverage*
 2 *under an MSA plan, no payment shall be made under*
 3 *paragraph (1) on behalf of an individual for a month*
 4 *unless the individual—*

5 *“(A) has established before the beginning of*
 6 *the month (or by such other deadline as the Sec-*
 7 *retary may specify) a MedicareAdvantage MSA*
 8 *(as defined in section 138(b)(2) of the Internal*
 9 *Revenue Code of 1986); and*

10 *“(B) if the individual has established more*
 11 *than 1 such MedicareAdvantage MSA, has des-*
 12 *ignated 1 of such accounts as the individual’s*
 13 *MedicareAdvantage MSA for purposes of this*
 14 *part.*

15 *Under rules under this section, such an individual*
 16 *may change the designation of such account under*
 17 *subparagraph (B) for purposes of this part.*

18 *“(3) LUMP-SUM DEPOSIT OF MEDICAL SAVINGS*
 19 *ACCOUNT CONTRIBUTION.—In the case of an indi-*
 20 *vidual electing an MSA plan effective beginning with*
 21 *a month in a year, the amount of the contribution to*
 22 *the MedicareAdvantage MSA on behalf of the indi-*
 23 *vidual for that month and all successive months in*
 24 *the year shall be deposited during that first month. In*
 25 *the case of a termination of such an election as of a*

1 month before the end of a year, the Secretary shall
 2 provide for a procedure for the recovery of deposits at-
 3 tributable to the remaining months in the year.

4 “(g) *PAYMENTS FROM TRUST FUNDS.*—Except as pro-
 5 vided in section 1858A(c) (relating to payments for quali-
 6 fied prescription drug coverage), the payment to a
 7 MedicareAdvantage organization under this section for in-
 8 dividuals enrolled under this part with the organization
 9 and payments to a MedicareAdvantage MSA under sub-
 10 section (e)(1) shall be made from the Federal Hospital In-
 11 surance Trust Fund and the Federal Supplementary Med-
 12 ical Insurance Trust Fund in such proportion as the Sec-
 13 retary determines reflects the relative weight that benefits
 14 under part A and under part B represents of the actuarial
 15 value of the total benefits under this title. Monthly pay-
 16 ments otherwise payable under this section for October 2000
 17 shall be paid on the first business day of such month.
 18 Monthly payments otherwise payable under this section for
 19 October 2001 shall be paid on the last business day of Sep-
 20 tember 2001. Monthly payments otherwise payable under
 21 this section for October 2006 shall be paid on the first busi-
 22 ness day of October 2006.

23 “(h) *SPECIAL RULE FOR CERTAIN INPATIENT HOS-*
 24 *PITAL STAYS.*—In the case of an individual who is receiv-
 25 ing inpatient hospital services from a subsection (d) hos-

1 *pital (as defined in section 1886(d)(1)(B)) as of the effective*
 2 *date of the individual's—*

3 “(1) *election under this part of a*
 4 *MedicareAdvantage plan offered by a*
 5 *MedicareAdvantage organization—*

6 “(A) *payment for such services until the*
 7 *date of the individual's discharge shall be made*
 8 *under this title through the MedicareAdvantage*
 9 *plan or the original medicare fee-for-service pro-*
 10 *gram option (as the case may be) elected before*
 11 *the election with such organization,*

12 “(B) *the elected organization shall not be fi-*
 13 *nancially responsible for payment for such serv-*
 14 *ices until the date after the date of the individ-*
 15 *ual's discharge; and*

16 “(C) *the organization shall nonetheless be*
 17 *paid the full amount otherwise payable to the or-*
 18 *ganization under this part; or*

19 “(2) *termination of election with respect to a*
 20 *MedicareAdvantage organization under this part—*

21 “(A) *the organization shall be financially*
 22 *responsible for payment for such services after*
 23 *such date and until the date of the individual's*
 24 *discharge;*

1 “(B) payment for such services during the
 2 stay shall not be made under section 1886(d) or
 3 by any succeeding MedicareAdvantage organiza-
 4 tion; and

5 “(C) the terminated organization shall not
 6 receive any payment with respect to the indi-
 7 vidual under this part during the period the in-
 8 dividual is not enrolled.

9 “(i) *SPECIAL RULE FOR HOSPICE CARE.*—

10 “(1) *INFORMATION.*—A contract under this part
 11 shall require the MedicareAdvantage organization to
 12 inform each individual enrolled under this part with
 13 a MedicareAdvantage plan offered by the organization
 14 about the availability of hospice care if—

15 “(A) a hospice program participating under
 16 this title is located within the organization’s
 17 service area; or

18 “(B) it is common practice to refer patients
 19 to hospice programs outside such service area.

20 “(2) *PAYMENT.*—If an individual who is enrolled
 21 with a MedicareAdvantage organization under this
 22 part makes an election under section 1812(d)(1) to re-
 23 ceive hospice care from a particular hospice
 24 program—

1 “(A) payment for the hospice care furnished
2 to the individual shall be made to the hospice
3 program elected by the individual by the Sec-
4 retary;

5 “(B) payment for other services for which
6 the individual is eligible notwithstanding the in-
7 dividual’s election of hospice care under section
8 1812(d)(1), including services not related to the
9 individual’s terminal illness, shall be made by
10 the Secretary to the MedicareAdvantage organi-
11 zation or the provider or supplier of the service
12 instead of payments calculated under subsection
13 (a); and

14 “(C) the Secretary shall continue to make
15 monthly payments to the MedicareAdvantage or-
16 ganization in an amount equal to the value of
17 the additional benefits required under section
18 1854(f)(1)(A).”.

19 **SEC. 204. SUBMISSION OF BIDS; PREMIUMS.**

20 Section 1854 (42 U.S.C. 1395w–24) is amended to
21 read as follows:

22 “SUBMISSION OF BIDS; PREMIUMS

23 “SEC. 1854. (a) SUBMISSION OF BIDS BY
24 MEDICAREADVANTAGE ORGANIZATIONS.—

25 “(1) IN GENERAL.—Not later than the second
26 Monday in September and except as provided in

1 paragraph (3), each MedicareAdvantage organization
 2 shall submit to the Secretary, in such form and man-
 3 ner as the Secretary may specify, for each
 4 MedicareAdvantage plan that the organization in-
 5 tends to offer in a service area in the following
 6 year—

7 “(A) notice of such intent and information
 8 on the service area of the plan;

9 “(B) the plan type for each plan;

10 “(C) if the MedicareAdvantage plan is a co-
 11 ordinated care plan (as described in section
 12 1851(a)(2)(A)) or a private fee-for-service plan
 13 (as described in section 1851(a)(2)(C)), the infor-
 14 mation described in paragraph (2) with respect
 15 to each payment area;

16 “(D) the enrollment capacity (if any) in re-
 17 lation to the plan and each payment area;

18 “(E) the expected mix, by health status, of
 19 enrolled individuals; and

20 “(F) such other information as the Sec-
 21 retary may specify.

22 “(2) INFORMATION REQUIRED FOR COORDINATED
 23 CARE PLANS AND PRIVATE FEE-FOR-SERVICE
 24 PLANS.—For a MedicareAdvantage plan that is a co-
 25 ordinated care plan (as described in section

1 *1851(a)(2)(A)) or a private fee-for-service plan (as*
 2 *described in section 1851(a)(2)(C)), the information*
 3 *described in this paragraph is as follows:*

4 “(A) INFORMATION REQUIRED WITH RE-
 5 SPECT TO BENEFITS UNDER THE ORIGINAL
 6 MEDICARE FEE-FOR-SERVICE PROGRAM OP-
 7 TION.—*Information relating to the coverage of*
 8 *benefits under the original medicare fee-for-serv-*
 9 *ice program option as follows:*

10 “(i) *The plan bid, which shall consist*
 11 *of a dollar amount that represents the total*
 12 *amount that the plan is willing to accept*
 13 *(not taking into account the application of*
 14 *the comprehensive risk adjustment method-*
 15 *ology under section 1853(a)(3)) for pro-*
 16 *viding coverage of the benefits under the*
 17 *original medicare fee-for-service program*
 18 *option to an individual enrolled in the plan*
 19 *that resides in the service area of the plan*
 20 *for a month.*

21 “(ii) *For the enhanced medical benefits*
 22 *package offered—*

23 “(I) *the adjusted community rate*
 24 *(as defined in subsection (g)(3)) of the*
 25 *package;*

1 “(II) the portion of the actuarial
2 value of such benefits package (if any)
3 that will be applied toward satisfying
4 the requirement for additional benefits
5 under subsection (g);

6 “(III) the MedicareAdvantage
7 monthly beneficiary premium for en-
8 hanced medical benefits (as defined in
9 subsection (b)(2)(C));

10 “(IV) a description of any cost-
11 sharing;

12 “(V) a description of whether the
13 amount of the unified deductible has
14 been lowered or the maximum limita-
15 tions on out-of-pocket expenses have
16 been decreased (relative to the levels
17 used in calculating the plan bid);

18 “(VI) such other information as
19 the Secretary considers necessary.

20 “(iii) The assumptions that the
21 MedicareAdvantage organization used in
22 preparing the plan bid with respect to num-
23 bers, in each payment area, of enrolled in-
24 dividuals and the mix, by health status, of
25 such individuals.

1 “(B) *INFORMATION REQUIRED WITH RE-*
 2 *SPECT TO PART D.—The information required to*
 3 *be submitted by an eligible entity under section*
 4 *1860D–12, including the monthly premiums for*
 5 *standard coverage and any other qualified pre-*
 6 *scription drug coverage available to individuals*
 7 *enrolled under part D.*

8 “(C) *DETERMINING PLAN COSTS INCLUDED*
 9 *IN PLAN BID.—For purposes of submitting its*
 10 *plan bid under subparagraph (A)(i) a*
 11 *MedicareAdvantage plan offered by a*
 12 *MedicareAdvantage organization satisfies sub-*
 13 *paragraphs (A) and (C) of section 1852(a)(1) if*
 14 *the actuarial value of the deductibles, coinsur-*
 15 *ance, and copayments applicable on average to*
 16 *individuals enrolled in such plan under this part*
 17 *with respect to benefits under the original medi-*
 18 *care fee-for-service program option on which that*
 19 *bid is based (ignoring any reduction in cost-*
 20 *sharing offered by such plan as enhanced med-*
 21 *ical benefits under paragraph (2)(A)(ii) or re-*
 22 *quired under clause (ii) or (iii) of subsection*
 23 *(g)(1)(C)) equals the amount specified in sub-*
 24 *section (f)(1)(B).*

1 “(3) *REQUIREMENTS FOR MSA PLANS.*—*For an*
 2 *MSA plan described in section 1851(a)(2)(B), the in-*
 3 *formation described in this paragraph is the informa-*
 4 *tion that such a plan would have been required to*
 5 *submit under this part if the Prescription Drug and*
 6 *Medicare Improvements Act of 2003 had not been en-*
 7 *acted.*

8 “(4) *REVIEW.*—

9 “(A) *IN GENERAL.*—*Subject to subpara-*
 10 *graph (B), the Secretary shall review the ad-*
 11 *justed community rates (as defined in section*
 12 *1854(g)(3)), the amounts of the*
 13 *MedicareAdvantage monthly basic premium and*
 14 *the MedicareAdvantage monthly beneficiary pre-*
 15 *mium for enhanced medical benefits filed under*
 16 *this subsection and shall approve or disapprove*
 17 *such rates and amounts so submitted. The Sec-*
 18 *retary shall review the actuarial assumptions*
 19 *and data used by the MedicareAdvantage organi-*
 20 *zation with respect to such rates and amounts so*
 21 *submitted to determine the appropriateness of*
 22 *such assumptions and data.*

23 “(B) *EXCEPTION.*—*The Secretary shall not*
 24 *review, approve, or disapprove the amounts sub-*
 25 *mitted under paragraph (3), or, with respect to*

1 *a private fee-for-service plan (as described in sec-*
 2 *tion 1851(a)(2)(C)) under subparagraph (A)(i),*
 3 *(A)(ii)(III), or (B) of paragraph (2).*

4 “(C) CLARIFICATION OF AUTHORITY RE-
 5 GARDING DISAPPROVAL OF UNREASONABLE BEN-
 6 EFICIARY COST-SHARING.—Under the authority
 7 under subparagraph (A), the Secretary may dis-
 8 approve the bid if the Secretary determines that
 9 the deductibles, coinsurance, or copayments ap-
 10 applicable under the plan discourage access to cov-
 11 ered services or are likely to result in favorable
 12 selection of MedicareAdvantage eligible individ-
 13 uals.

14 “(5) APPLICATION OF FEHBP STANDARD; PROHI-
 15 BITION ON PRICE GOUGING.—Each bid amount sub-
 16 mitted under paragraph (1) for a MedicareAdvantage
 17 plan must reasonably and equitably reflect the cost of
 18 benefits provided under that plan.

19 “(b) MONTHLY PREMIUMS CHARGED.—

20 “(1) IN GENERAL.—

21 “(A) COORDINATED CARE AND PRIVATE
 22 FEE-FOR-SERVICE PLANS.—The monthly amount
 23 of the premium charged to an individual en-
 24 rolled in a MedicareAdvantage plan (other than
 25 an MSA plan) offered by a MedicareAdvantage

1 organization shall be equal to the sum of the fol-
2 lowing:

3 “(i) *The MedicareAdvantage monthly*
4 *basic beneficiary premium (if any).*

5 “(ii) *The MedicareAdvantage monthly*
6 *beneficiary premium for enhanced medical*
7 *benefits (if any).*

8 “(iii) *The MedicareAdvantage monthly*
9 *obligation for qualified prescription drug*
10 *coverage (if any).*

11 “(B) *MSA PLANS.—The rules under this*
12 *section that would have applied with respect to*
13 *an MSA plan if the Prescription Drug and*
14 *Medicare Improvements Act of 2003 had not*
15 *been enacted shall continue to apply to MSA*
16 *plans after the date of enactment of such Act.*

17 “(2) *PREMIUM TERMINOLOGY.—For purposes of*
18 *this part:*

19 “(A) *MEDICAREADVANTAGE MONTHLY BASIC*
20 *BENEFICIARY PREMIUM.—The term*
21 *‘MedicareAdvantage monthly basic beneficiary*
22 *premium’ means, with respect to a*
23 *MedicareAdvantage plan, the amount required to*
24 *be charged under subsection (d)(2) for the plan.*

1 “(B) *MEDICAREADVANTAGE MONTHLY BEN-*
 2 *EFICIARY OBLIGATION FOR QUALIFIED PRESCRIP-*
 3 *TION DRUG COVERAGE.*—*The term*
 4 *‘MedicareAdvantage monthly beneficiary obliga-*
 5 *tion for qualified prescription drug coverage’*
 6 *means, with respect to a MedicareAdvantage*
 7 *plan, the amount determined under section*
 8 *1858A(d).*

9 “(C) *MEDICAREADVANTAGE MONTHLY BEN-*
 10 *EFICIARY PREMIUM FOR ENHANCED MEDICAL*
 11 *BENEFITS.*—*The term ‘MedicareAdvantage*
 12 *monthly beneficiary premium for enhanced med-*
 13 *ical benefits’ means, with respect to a*
 14 *MedicareAdvantage plan, the amount required to*
 15 *be charged under subsection (f)(2) for the plan,*
 16 *or, in the case of an MSA plan, the amount filed*
 17 *under subsection (a)(3).*

18 “(D) *MEDICAREADVANTAGE MONTHLY MSA*
 19 *PREMIUM.*—*The term ‘MedicareAdvantage*
 20 *monthly MSA premium’ means, with respect to*
 21 *a MedicareAdvantage plan, the amount of such*
 22 *premium filed under subsection (a)(3) for the*
 23 *plan.*

24 “(c) *UNIFORM PREMIUM.*—*The MedicareAdvantage*
 25 *monthly basic beneficiary premium, the MedicareAdvantage*

1 monthly beneficiary obligation for qualified prescription
 2 drug coverage, the MedicareAdvantage monthly beneficiary
 3 premium for enhanced medical benefits, and the
 4 MedicareAdvantage monthly MSA premium charged under
 5 subsection (b) of a MedicareAdvantage organization under
 6 this part may not vary among individuals enrolled in the
 7 plan. Subject to the provisions of section 1858(h), such re-
 8 quirement shall not apply to enrollees of a
 9 MedicareAdvantage plan who are enrolled in the plan pur-
 10 suant to a contractual agreement between the plan and an
 11 employer or other group health plan that provides employ-
 12 ment-based retiree health coverage (as defined in section
 13 1860D–20(d)(4)(B)) if the premium amount is the same for
 14 all such enrollees under such agreement.

15 “(d) *DETERMINATION OF PREMIUM REDUCTIONS, RE-*
 16 *DUCE COST-SHARING, ADDITIONAL BENEFITS, AND BENE-*
 17 *FICIARY PREMIUMS.*—

18 “(1) *BIDS BELOW THE BENCHMARK.*—If the Sec-
 19 retary determines under section 1853(d)(3) that the
 20 weighted service area benchmark amount exceeds the
 21 plan bid, the Secretary shall require the plan to pro-
 22 vide additional benefits in accordance with subsection
 23 (g).

24 “(2) *BIDS ABOVE THE BENCHMARK.*—If the Sec-
 25 retary determines under section 1853(d)(3) that the

1 *plan bid exceeds the weighted service area benchmark*
 2 *amount (determined under section 1853(d)(2)), the*
 3 *amount of such excess shall be the MedicareAdvantage*
 4 *monthly basic beneficiary premium (as defined in*
 5 *section 1854(b)(2)(A)).*

6 “(e) *TERMS AND CONDITIONS OF IMPOSING PRE-*
 7 *MIUMS.—Each MedicareAdvantage organization shall per-*
 8 *mit the payment of any MedicareAdvantage monthly basic*
 9 *premium, the MedicareAdvantage monthly beneficiary obli-*
 10 *gation for qualified prescription drug coverage, and the*
 11 *MedicareAdvantage monthly beneficiary premium for en-*
 12 *hanced medical benefits on a monthly basis, may terminate*
 13 *election of individuals for a MedicareAdvantage plan for*
 14 *failure to make premium payments only in accordance with*
 15 *section 1851(g)(3)(B)(i), and may not provide for cash or*
 16 *other monetary rebates as an inducement for enrollment or*
 17 *otherwise (other than as an additional benefit described in*
 18 *subsection (g)(1)(C)(i)).*

19 “(f) *LIMITATION ON ENROLLEE LIABILITY.—*

20 “(1) *FOR BENEFITS UNDER THE ORIGINAL MEDI-*
 21 *CARE FEE-FOR-SERVICE PROGRAM OPTION.—The sum*
 22 *of—*

23 “(A) *the MedicareAdvantage monthly basic*
 24 *beneficiary premium (multiplied by 12) and the*
 25 *actuarial value of the deductibles, coinsurance,*

1 *and copayments (determined on the same basis*
 2 *as used in determining the plan’s bid under*
 3 *paragraph (2)(C)) applicable on average to indi-*
 4 *viduals enrolled under this part with a*
 5 *MedicareAdvantage plan described in subpara-*
 6 *graph (A) of section 1851(a)(2) of an organiza-*
 7 *tion with respect to required benefits described in*
 8 *section 1852(a)(1)(A); must equal*

9 *“(B) the actuarial value of the deductibles,*
 10 *coinsurance, and copayments that would be ap-*
 11 *plicable on average to individuals who have*
 12 *elected to receive benefits under the original*
 13 *medicare fee-for-service program option if such*
 14 *individuals were not members of a*
 15 *MedicareAdvantage organization for the year*
 16 *(adjusted as determined appropriate by the Sec-*
 17 *retary to account for geographic differences and*
 18 *for plan cost and utilization differences).*

19 *“(2) FOR ENHANCED MEDICAL BENEFITS.—If the*
 20 *MedicareAdvantage organization provides to its mem-*
 21 *bers enrolled under this part in a MedicareAdvantage*
 22 *plan described in subparagraph (A) of section*
 23 *1851(a)(2) with respect to enhanced medical benefits*
 24 *relating to benefits under the original medicare fee-*
 25 *for-service program option, the sum of the*

1 *MedicareAdvantage* monthly beneficiary premium for
 2 enhanced medical benefits (multiplied by 12) charged
 3 and the actuarial value of its deductibles, coinsur-
 4 ance, and copayments charged with respect to such
 5 benefits for a year must equal the adjusted commu-
 6 nity rate (as defined in subsection (g)(3)) for such
 7 benefits for the year minus the actuarial value of any
 8 additional benefits pursuant to clause (ii), (iii), or
 9 (iv) of subsection (g)(2)(C) that the plan specified
 10 under subsection (a)(2)(i)(II).

11 “(3) *DETERMINATION ON OTHER BASIS.*—If the
 12 Secretary determines that adequate data are not
 13 available to determine the actuarial value under
 14 paragraph (1)(A) or (2), the Secretary may determine
 15 such amount with respect to all individuals in the
 16 same geographic area, the State, or in the United
 17 States, eligible to enroll in the *MedicareAdvantage*
 18 plan involved under this part or on the basis of other
 19 appropriate data.

20 “(4) *SPECIAL RULE FOR PRIVATE FEE-FOR-SERV-*
 21 *ICE PLANS.*—With respect to a *MedicareAdvantage*
 22 private fee-for-service plan (other than a plan that is
 23 an MSA plan), in no event may—

24 “(A) the actuarial value of the deductibles,
 25 coinsurance, and copayments applicable on aver-

age to individuals enrolled under this part with such a plan of an organization with respect to required benefits described in subparagraphs (A), (C), and (D) of section 1852(a)(1); exceed

“(B) the actuarial value of the deductibles, coinsurance, and copayments that would be applicable on average to individuals entitled to (or enrolled for) benefits under part A and enrolled under part B if they were not members of a MedicareAdvantage organization for the year.

“(g) REQUIREMENT FOR ADDITIONAL BENEFITS.—

“(1) REQUIREMENT.—

“(A) IN GENERAL.—Each MedicareAdvantage organization (in relation to a MedicareAdvantage plan, other than an MSA plan, it offers) shall provide that if there is an excess amount (as defined in subparagraph (B)) for the plan for a contract year, subject to the succeeding provisions of this subsection, the organization shall provide to individuals such additional benefits described in subparagraph (C) as the organization may specify in a value which the Secretary determines is at least equal to the adjusted excess amount (as defined in subparagraph (D)).

1 “(B) *EXCESS AMOUNT.*—For purposes of
 2 this paragraph, the term ‘excess amount’ means,
 3 for an organization for a plan, is 100 percent of
 4 the amount (if any) by which the weighted serv-
 5 ice area benchmark amount (determined under
 6 section 1853(d)(2)) exceeds the plan bid (as ad-
 7 justed under section 1853(d)(1)).

8 “(C) *ADDITIONAL BENEFITS DESCRIBED.*—
 9 The additional benefits described in this sub-
 10 paragraph are as follows:

11 “(i) Subject to subparagraph (F), a
 12 monthly part B premium reduction for in-
 13 dividuals enrolled in the plan.

14 “(ii) Lowering the amount of the uni-
 15 fied deductible and decreasing the max-
 16 imum limitations on out-of-pocket expenses
 17 for individuals enrolled in the plan.

18 “(iii) A reduction in the actuarial
 19 value of plan cost-sharing for plan enrollees.

20 “(iv) Subject to subparagraph (E),
 21 such additional benefits as the organization
 22 may specify.

23 “(v) Contributing to the stabilization
 24 fund under paragraph (2).

1 “(vi) *Any combination of the reduc-*
 2 *tions and benefits described in clauses (i)*
 3 *through (v).*

4 “(D) *ADJUSTED EXCESS AMOUNT.—For*
 5 *purposes of this paragraph, the term ‘adjusted*
 6 *excess amount’ means, for an organization for a*
 7 *plan, is the excess amount reduced to reflect any*
 8 *amount withheld and reserved for the organiza-*
 9 *tion for the year under paragraph (2).*

10 “(E) *RULE FOR APPROVAL OF MEDICAL AND*
 11 *PRESCRIPTION DRUG BENEFITS.—An organiza-*
 12 *tion may not specify any additional benefit that*
 13 *provides for the coverage of any prescription*
 14 *drug (other than that relating to prescription*
 15 *drugs covered under the original medicare fee-*
 16 *for-service program option).*

17 “(F) *PREMIUM REDUCTIONS.—*

18 “(i) *IN GENERAL.—Subject to clause*
 19 *(ii), as part of providing any additional*
 20 *benefits required under subparagraph (A), a*
 21 *MedicareAdvantage organization may elect*
 22 *a reduction in its payments under section*
 23 *1853(a)(1)(A)(i) with respect to a*
 24 *MedicareAdvantage plan and the Secretary*
 25 *shall apply such reduction to reduce the*

1 *premium under section 1839 of each en-*
 2 *rollee in such plan as provided in section*
 3 *1840(i).*

4 “(ii) *AMOUNT OF REDUCTION.*—*The*
 5 *amount of the reduction under clause (i)*
 6 *with respect to any enrollee in a*
 7 *MedicareAdvantage plan—*

8 *“(I) may not exceed 125 percent*
 9 *of the premium described under section*
 10 *1839(a)(3); and*

11 *“(II) shall apply uniformly to*
 12 *each enrollee of the MedicareAdvantage*
 13 *plan to which such reduction applies.*

14 “(G) *UNIFORM APPLICATION.*—*This para-*
 15 *graph shall be applied uniformly for all enrollees*
 16 *for a plan.*

17 “(H) *CONSTRUCTION.*—*Nothing in this sub-*
 18 *section shall be construed as preventing a*
 19 *MedicareAdvantage organization from providing*
 20 *enhanced medical benefits (described in section*
 21 *1852(a)(3)) that are in addition to the health*
 22 *care benefits otherwise required to be provided*
 23 *under this paragraph and from imposing a pre-*
 24 *mium for such enhanced medical benefits.*

1 “(2) *STABILIZATION* *FUND.—A*
2 *MedicareAdvantage organization may provide that a*
3 *part of the value of an excess amount described in*
4 *paragraph (1) be withheld and reserved in the Fed-*
5 *eral Hospital Insurance Trust Fund and in the Fed-*
6 *eral Supplementary Medical Insurance Trust Fund*
7 *(in such proportions as the Secretary determines to be*
8 *appropriate) by the Secretary for subsequent annual*
9 *contract periods, to the extent required to prevent*
10 *undue fluctuations in the additional benefits offered*
11 *in those subsequent periods by the organization in ac-*
12 *cordance with such paragraph. Any of such value of*
13 *the amount reserved which is not provided as addi-*
14 *tional benefits described in paragraph (1)(A) to indi-*
15 *viduals electing the MedicareAdvantage plan of the*
16 *organization in accordance with such paragraph*
17 *prior to the end of such periods, shall revert for the*
18 *use of such Trust Funds.*

19 “(3) *ADJUSTED COMMUNITY RATE.—For pur-*
20 *poses of this subsection, subject to paragraph (4), the*
21 *term ‘adjusted community rate’ for a service or serv-*
22 *ices means, at the election of a MedicareAdvantage or-*
23 *ganization, either—*

24 “(A) *the rate of payment for that service or*
25 *services which the Secretary annually determines*

1 *would apply to an individual electing a*
2 *MedicareAdvantage plan under this part if the*
3 *rate of payment were determined under a ‘com-*
4 *munity rating system’ (as defined in section*
5 *1302(8) of the Public Health Service Act, other*
6 *than subparagraph (C)); or*

7 *“(B) such portion of the weighted aggregate*
8 *premium, which the Secretary annually esti-*
9 *mates would apply to such an individual, as the*
10 *Secretary annually estimates is attributable to*
11 *that service or services,*

12 *but adjusted for differences between the utilization*
13 *characteristics of the individuals electing coverage*
14 *under this part and the utilization characteristics of*
15 *the other enrollees with the plan (or, if the Secretary*
16 *finds that adequate data are not available to adjust*
17 *for those differences, the differences between the utili-*
18 *zation characteristics of individuals selecting other*
19 *MedicareAdvantage coverage, or MedicareAdvantage*
20 *eligible individuals in the area, in the State, or in the*
21 *United States, eligible to elect MedicareAdvantage*
22 *coverage under this part and the utilization charac-*
23 *teristics of the rest of the population in the area, in*
24 *the State, or in the United States, respectively).*

1 “(4) *DETERMINATION BASED ON INSUFFICIENT*
2 *DATA.*—For purposes of this subsection, if the Sec-
3 retary finds that there is insufficient enrollment expe-
4 rience to determine the average amount of payments
5 to be made under this part at the beginning of a con-
6 tract period or to determine (in the case of a newly
7 operated provider-sponsored organization or other
8 new organization) the adjusted community rate for
9 the organization, the Secretary may determine such
10 an average based on the enrollment experience of other
11 contracts entered into under this part and may deter-
12 mine such a rate using data in the general commer-
13 cial marketplace.

14 “(h) *PROHIBITION OF STATE IMPOSITION OF PREMIUM*
15 *TAXES.*—No State may impose a premium tax or similar
16 tax with respect to payments to MedicareAdvantage organi-
17 zations under section 1853.

18 “(i) *PERMITTING USE OF SEGMENTS OF SERVICE*
19 *AREAS.*—The Secretary shall permit a MedicareAdvantage
20 organization to elect to apply the provisions of this section
21 uniformly to separate segments of a service area (rather
22 than uniformly to an entire service area) as long as such
23 segments are composed of 1 or more MedicareAdvantage
24 payment areas.”.

1 (b) *STUDY AND REPORT ON CLARIFICATION OF AU-*
 2 *THORITY REGARDING DISAPPROVAL OF UNREASONABLE*
 3 *BENEFICIARY COST-SHARING.*—

4 (1) *STUDY.*—*The Secretary, in consultation with*
 5 *beneficiaries, consumer groups, employers, and*
 6 *Medicare+Choice organizations, shall conduct a study*
 7 *to determine the extent to which the cost-sharing*
 8 *structures under Medicare+Choice plans under part*
 9 *C of title XVIII of the Social Security Act discourage*
 10 *access to covered services or discriminate based on the*
 11 *health status of Medicare+Choice eligible individuals*
 12 *(as defined in section 1851(a)(3) of the Social Secu-*
 13 *rity Act (42 U.S.C. 1395w–21(a)(3))).*

14 (2) *REPORT.*—*Not later than December 31, 2004,*
 15 *the Secretary shall submit a report to Congress on the*
 16 *study conducted under paragraph (1) together with*
 17 *recommendations for such legislation and administra-*
 18 *tive actions as the Secretary considers appropriate.*

19 **SEC. 205. SPECIAL RULES FOR PRESCRIPTION DRUG BENE-**
 20 **FITS.**

21 *Part C of title XVIII (42 U.S.C. 1395w–21 et seq.)*
 22 *is amended by inserting after section 1857 the following*
 23 *new section:*

24 “*SPECIAL RULES FOR PRESCRIPTION DRUG BENEFITS*

25 “*SEC. 1858A. (a) AVAILABILITY.*—

1 “(1) *PLANS REQUIRED TO PROVIDE QUALIFIED*
 2 *PRESCRIPTION DRUG COVERAGE TO ENROLLEES.*—

3 “(A) *IN GENERAL.*—*Except as provided in*
 4 *subparagraph (B), on and after January 1,*
 5 *2006, a MedicareAdvantage organization offering*
 6 *a MedicareAdvantage plan (except for an MSA*
 7 *plan) shall make available qualified prescription*
 8 *drug coverage that meets the requirements for*
 9 *such coverage under this part and part D to each*
 10 *enrollee of the plan.*

11 “(B) *PRIVATE FEE-FOR-SERVICE PLANS*
 12 *MAY, BUT ARE NOT REQUIRED TO, PROVIDE*
 13 *QUALIFIED PRESCRIPTION DRUG COVERAGE.*—
 14 *Pursuant to section 1852(a)(2)(D), a private fee-*
 15 *for-service plan may elect not to provide quali-*
 16 *fied prescription drug coverage under part D to*
 17 *individuals residing in the area served by the*
 18 *plan.*

19 “(2) *REFERENCE TO PROVISION PERMITTING AD-*
 20 *DITIONAL PRESCRIPTION DRUG COVERAGE.*—*For the*
 21 *provisions of part D, made applicable to this part*
 22 *pursuant to paragraph (1), that permit a plan to*
 23 *make available qualified prescription drug coverage*
 24 *that includes coverage of covered drugs that exceeds*
 25 *the coverage required under paragraph (1) of section*

1 1860D–6 in an area, but only if the
 2 *MedicareAdvantage* organization offering the plan
 3 also offers a *MedicareAdvantage* plan in the area that
 4 only provides the coverage that is required under such
 5 paragraph (1), see paragraph (2) of such section.

6 “(3) *RULE FOR APPROVAL OF MEDICAL AND PRE-*
 7 *SCRIPTION DRUG BENEFITS.*—Pursuant to sections
 8 1854(g)(1)(F) and 1852(a)(3)(D), a
 9 *MedicareAdvantage* organization offering a
 10 *MedicareAdvantage* plan that provides qualified pre-
 11 scription drug coverage may not make available cov-
 12 erage of any prescription drugs (other than that relat-
 13 ing to prescription drugs covered under the original
 14 *medicare fee-for-service* program option) to an en-
 15 rollee as an additional benefit or as an enhanced
 16 medical benefit.

17 “(b) *COMPLIANCE WITH ADDITIONAL BENEFICIARY*
 18 *PROTECTIONS.*—With respect to the offering of qualified
 19 prescription drug coverage by a *MedicareAdvantage* organi-
 20 zation under a *MedicareAdvantage* plan, the organization
 21 and plan shall meet the requirements of section 1860D–5,
 22 including requirements relating to information dissemina-
 23 tion and grievance and appeals, and such other require-
 24 ments under part D that the Secretary determines appro-
 25 priate in the same manner as such requirements apply to

1 *an eligible entity and a Medicare Prescription Drug plan*
 2 *under part D. The Secretary shall waive such requirements*
 3 *to the extent the Secretary determines that such require-*
 4 *ments duplicate requirements otherwise applicable to the or-*
 5 *ganization or the plan under this part.*

6 “(c) *PAYMENTS FOR PRESCRIPTION DRUGS.*—

7 “(1) *PAYMENT OF FULL AMOUNT OF PREMIUM TO*
 8 *ORGANIZATIONS FOR QUALIFIED PRESCRIPTION DRUG*
 9 *COVERAGE.*—

10 “(A) *IN GENERAL.*—*For each year (begin-*
 11 *ning with 2006), the Secretary shall pay to each*
 12 *MedicareAdvantage organization offering a*
 13 *MedicareAdvantage plan that provides qualified*
 14 *prescription drug coverage, an amount equal to*
 15 *the full amount of the monthly premium sub-*
 16 *mitted under section 1854(a)(2)(B) for the year,*
 17 *as adjusted using the risk adjusters that apply to*
 18 *the standard prescription drug coverage pub-*
 19 *lished under section 1860D–11.*

20 “(B) *APPLICATION OF PART D RISK COR-*
 21 *RIDOR, STABILIZATION RESERVE FUND, AND AD-*
 22 *MINISTRATIVE EXPENSES PROVISIONS.*—*The pro-*
 23 *visions of subsections (b), (c), and (d) of section*
 24 *1860D–16 shall apply to a MedicareAdvantage*
 25 *organization offering a MedicareAdvantage plan*

1 that provides qualified prescription drug cov-
 2 erage and payments made to such organization
 3 under subparagraph (A) in the same manner as
 4 such provisions apply to an eligible entity offer-
 5 ing a Medicare Prescription Drug plan and pay-
 6 ments made to such entity under subsection (a)
 7 of section 1860D–16.

8 “(2) *PAYMENT FROM PRESCRIPTION DRUG AC-*
 9 *COUNT.—Payment made to MedicareAdvantage orga-*
 10 *nizations under this subsection shall be made from the*
 11 *Prescription Drug Account in the Federal Supple-*
 12 *mentary Medical Insurance Trust Fund under section*
 13 *1841.*

14 “(d) *COMPUTATION OF MEDICAREADVANTAGE MONTH-*
 15 *LY BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIP-*
 16 *TION DRUG COVERAGE.—In the case of a*
 17 *MedicareAdvantage eligible individual receiving qualified*
 18 *prescription drug coverage under a MedicareAdvantage*
 19 *plan during a year after 2005, the MedicareAdvantage*
 20 *monthly beneficiary obligation for qualified prescription*
 21 *drug coverage of such individual in the year shall be deter-*
 22 *mined in the same manner as the monthly beneficiary obli-*
 23 *gation is determined under section 1860D–17 for eligible*
 24 *beneficiaries enrolled in a Medicare Prescription Drug*
 25 *plan, except that, for purposes of this subparagraph, any*

1 *reference to the monthly plan premium approved by the*
 2 *Secretary under section 1860D–13 shall be treated as a ref-*
 3 *erence to the monthly premium for qualified prescription*
 4 *drug coverage submitted by the MedicareAdvantage organi-*
 5 *zation offering the plan under section 1854(a)(2)(A) and*
 6 *approved by the Secretary.*

7 “(e) *COLLECTION OF MEDICAREADVANTAGE MONTHLY*
 8 *BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIPTION*
 9 *DRUG COVERAGE.*—*The provisions of section 1860D–18,*
 10 *including subsection (b) of such section, shall apply to the*
 11 *amount of the MedicareAdvantage monthly beneficiary obli-*
 12 *gation for qualified prescription drug coverage (as deter-*
 13 *mined under subsection (d)) required to be paid by a*
 14 *MedicareAdvantage eligible individual enrolled in a*
 15 *MedicareAdvantage plan in the same manner as such provi-*
 16 *sions apply to the amount of the monthly beneficiary obli-*
 17 *gation required to be paid by an eligible beneficiary en-*
 18 *rolled in a Medicare Prescription Drug plan under part*
 19 *D.*

20 “(f) *AVAILABILITY OF PREMIUM SUBSIDY AND COST-*
 21 *SHARING REDUCTIONS FOR LOW-INCOME ENROLLEES AND*
 22 *REINSURANCE PAYMENTS.*—*For provisions—*

23 “(1) *providing premium subsidies and cost-shar-*
 24 *ing reductions for low-income individuals receiving*

1 *qualified prescription drug coverage through a*
 2 *MedicareAdvantage plan, see section 1860D–19; and*
 3 “(2) *providing a MedicareAdvantage organiza-*
 4 *tion with reinsurance payments for certain expenses*
 5 *incurred in providing qualified prescription drug cov-*
 6 *erage through a MedicareAdvantage plan, see section*
 7 *1860D–20.”.*

8 (b) *TREATMENT OF REDUCTION FOR PURPOSES OF*
 9 *DETERMINING GOVERNMENT CONTRIBUTION UNDER PART*
 10 *B.—Section 1844(c) (42 U.S.C. 1395w) is amended by*
 11 *striking “section 1854(f)(1)(E)” and inserting “section*
 12 *1854(d)(1)(A)(i)”.*

13 **SEC. 206. FACILITATING EMPLOYER PARTICIPATION.**

14 *Section 1858(h) (as added by section 211) is*
 15 *amended—*

16 (1) *by inserting “(including subsection (i) of*
 17 *such section)” after “section 1857”; and*

18 (2) *by adding at the end the following new sen-*
 19 *tence: “In applying the authority under section*
 20 *1857(i) pursuant to this subsection, the Adminis-*
 21 *trator may permit MedicareAdvantage plans to estab-*
 22 *lish separate premium amounts for enrollees in an*
 23 *employer or other group health plan that provides*
 24 *employment-based retiree health coverage (as defined*
 25 *in section 1860D–20(d)(4)(B)).”*

1 **SEC. 207. ADMINISTRATION BY THE CENTER FOR MEDICARE**
 2 **CHOICES.**

3 *On and after January 1, 2006, the MedicareAdvantage*
 4 *program under part C of title XVIII of the Social Security*
 5 *Act shall be administered by the Center for Medicare*
 6 *Choices established under section 1808 such title (as added*
 7 *by section 301), and each reference to the Secretary made*
 8 *in such part shall be deemed to be a reference to the Admin-*
 9 *istrator of the Center for Medicare Choices.*

10 **SEC. 208. CONFORMING AMENDMENTS.**

11 *(a) ORGANIZATIONAL AND FINANCIAL REQUIREMENTS*
 12 *FOR MEDICAREADVANTAGE ORGANIZATIONS; PROVIDER-*
 13 *SPONSORED ORGANIZATIONS.—Section 1855 (42 U.S.C.*
 14 *1395w–25) is amended—*

15 *(1) in subsection (b), in the matter preceding*
 16 *paragraph (1), by inserting “subparagraphs (A), (B),*
 17 *and (D) of” before “section 1852(A)(1)”; and*

18 *(2) by striking “Medicare+Choice” and insert-*
 19 *ing “MedicareAdvantage” each place it appears.*

20 *(b) ESTABLISHMENT OF PSO STANDARDS.—Section*
 21 *1856 (42 U.S.C. 1395w–26) is amended by striking*
 22 *“Medicare+Choice” and inserting “MedicareAdvantage”*
 23 *each place it appears.*

24 *(c) CONTRACTS WITH MEDICAREADVANTAGE ORGANI-*
 25 *ZATIONS.—Section 1857 (42 U.S.C. 1395w–27) is*
 26 *amended—*

1 (1) in subsection (g)(1)—

2 (A) in subparagraph (B), by striking
3 “amount of the Medicare+Choice monthly basic
4 and supplemental beneficiary premiums” and
5 inserting “amounts of the MedicareAdvantage
6 monthly basic premium and MedicareAdvantage
7 monthly beneficiary premium for enhanced med-
8 ical benefits”;

9 (B) in subparagraph (F), by striking “or”
10 after the semicolon at the end;

11 (C) in subparagraph (G), by adding “or”
12 after the semicolon at the end; and

13 (D) by inserting after subparagraph (G) the
14 following new subparagraph:

15 “(H)(i) charges any individual an amount
16 in excess of the MedicareAdvantage monthly ben-
17 eficiary obligation for qualified prescription
18 drug coverage under section 1858A(d);

19 “(ii) provides coverage for prescription
20 drugs that is not qualified prescription drug cov-
21 erage;

22 “(iii) offers prescription drug coverage, but
23 does not make standard prescription drug cov-
24 erage available; or

1 “(iv) provides coverage for prescription
 2 drugs (other than that relating to prescription
 3 drugs covered under the original medicare fee-
 4 for-service program option described in section
 5 1851(a)(1)(A)(i)) as an enhanced medical benefit
 6 under section 1852(a)(3)(D) or as an additional
 7 benefit under section 1854(g)(1)(F),”; and
 8 (2) by striking “Medicare+Choice” and insert-
 9 ing “MedicareAdvantage” each place it appears.

10 (d) *DEFINITIONS; MISCELLANEOUS PROVISIONS.*—Sec-
 11 tion 1859 (42 U.S.C. 1395w–28) is amended—

12 (1) by striking subsection (c) and inserting the
 13 following new subsection:

14 “(c) *OTHER REFERENCES TO OTHER TERMS.*—

15 “(1) *ENHANCED MEDICAL BENEFITS.*—The term
 16 ‘enhanced medical benefits’ is defined in section
 17 1852(a)(3)(E).

18 “(2) *MEDICAREADVANTAGE ELIGIBLE INDIVIDUAL.*—The term ‘MedicareAdvantage eligible indi-
 19 vidual’ is defined in section 1851(a)(3).
 20

21 “(3) *MEDICAREADVANTAGE PAYMENT AREA.*—
 22 The term ‘MedicareAdvantage payment area’ is de-
 23 fined in section 1853(d).

24 “(4) *NATIONAL PER CAPITA MEDICARE+CHOICE*
 25 *GROWTH PERCENTAGE.*—The ‘national per capita

1 *Medicare+Choice growth percentage’ is defined in sec-*
 2 *tion 1853(c)(6).*

3 “(5) *MEDICAREADVANTAGE MONTHLY BASIC BEN-*
 4 *EFICIARY PREMIUM; MEDICAREADVANTAGE MONTHLY*
 5 *BENEFICIARY OBLIGATION FOR QUALIFIED PRESCRIP-*
 6 *TION DRUG COVERAGE; MEDICAREADVANTAGE MONTH-*
 7 *LY BENEFICIARY PREMIUM FOR ENHANCED MEDICAL*
 8 *BENEFITS.—The terms ‘MedicareAdvantage monthly*
 9 *basic beneficiary premium’, ‘MedicareAdvantage*
 10 *monthly beneficiary obligation for qualified prescrip-*
 11 *tion drug coverage’, and ‘MedicareAdvantage monthly*
 12 *beneficiary premium for enhanced medical benefits’*
 13 *are defined in section 1854(b)(2).*

14 “(6) *QUALIFIED PRESCRIPTION DRUG COV-*
 15 *ERAGE.—The term ‘qualified prescription drug cov-*
 16 *erage’ has the meaning given such term in section*
 17 *1860D(9).*

18 “(7) *STANDARD PRESCRIPTION DRUG COV-*
 19 *ERAGE.—The term ‘standard prescription drug cov-*
 20 *erage’ has the meaning given such term in section*
 21 *1860D(10).’; and*

22 *(2) by striking “Medicare+Choice” and insert-*
 23 *ing “MedicareAdvantage” each place it appears.*

24 *(e) CONFORMING AMENDMENTS EFFECTIVE BEFORE*
 25 *2006.—*

1 (1) *EXTENSION OF MSAS.—Section 1851(b)(4)*
 2 *(42 U.S.C. 1395w–21(b)(4)) is amended by striking*
 3 *“January 1, 2003” and inserting “January 1, 2004”.*

4 (2) *CONTINUOUS OPEN ENROLLMENT AND*
 5 *DISENROLLMENT THROUGH 2005.—Section 1851(e) of*
 6 *the Social Security Act (42 U.S.C. 1395w–21(e)) is*
 7 *amended—*

8 (A) *in paragraph (2)(A), by striking*
 9 *“THROUGH 2004” and “December 31, 2004” and*
 10 *inserting “THROUGH 2005” and “December 31,*
 11 *2005”, respectively;*

12 (B) *in the heading of paragraph (2)(B), by*
 13 *striking “DURING 2005” and inserting “DURING*
 14 *2006”;*

15 (C) *in paragraphs (2)(B)(i) and (2)(C)(i),*
 16 *by striking “2005” and inserting “2006” each*
 17 *place it appears;*

18 (D) *in paragraph (2)(D), by striking*
 19 *“2004” and inserting “2005”; and*

20 (E) *in paragraph (4), by striking “2005”*
 21 *and inserting “2006” each place it appears.*

22 (3) *UPDATE IN MINIMUM PERCENTAGE IN-*
 23 *CREASE.—Section 1853(c)(1)(C) (42 U.S.C. 1395w–*
 24 *23(c)(1)(C)) is amended by striking clause (iv) and*
 25 *inserting the following new clauses:*

1 “(iv) For 2002, 2003, and 2004, 102
 2 percent of the annual Medicare+Choice
 3 capitation rate under this paragraph for
 4 the area for the previous year.

5 “(v) For 2005, 103 percent of the an-
 6 nual Medicare+Choice capitation rate
 7 under this paragraph for the area for 2003.

8 “(vi) For 2006 and each succeeding
 9 year, 102 percent of the annual
 10 Medicare+Choice capitation rate under this
 11 paragraph for the area for the previous
 12 year, except that such rate shall be deter-
 13 mined by substituting ‘102’ for ‘103’ in
 14 clause (v).”.

15 (4) *EFFECTIVE DATE.*—The amendments made
 16 by this subsection shall take effect on the date of en-
 17 actment of this Act.

18 (e) *OTHER CONFORMING AMENDMENTS.*—

19 (1) *CONFORMING MEDICARE CROSS-REF-*
 20 *ERENCES.*—

21 (A) Section 1839(a)(2) (42 U.S.C.
 22 1395r(a)(2)) is amended by striking “section
 23 1854(f)(1)(E)” and inserting “section
 24 1854(g)(1)(C)(i)”.

1 (B) Section 1840(i) (42 U.S.C. 1395s(i)) is
 2 amended by striking “section 1854(f)(1)(E)” and
 3 inserting “section 1854(g)(1)(C)(i)”.

4 (C) Section 1844(c) (42 U.S.C. 1395w(c)) is
 5 amended by striking “section 1854(f)(1)(E)” and
 6 inserting “section 1854(g)(1)(C)(i)”.

7 (D) Section 1876(k)(3)(A) (42 U.S.C.
 8 1395mm(k)(3)(A)) is amended by inserting “(as
 9 in effect immediately before the enactment of the
 10 Prescription Drug and Medicare Improvements
 11 Act of 2003)” after section 1853(a).

12 (F) Section 1876(k)(4) (42 U.S.C.
 13 1395mm(k)(4)(A)) is amended—

14 (i) in subparagraph (A), by striking
 15 “section 1853(a)(3)(B)” and inserting “sec-
 16 tion 1853(a)(3)(D)”;

17 (ii) in subparagraph (B), by striking
 18 “section 1854(g)” and inserting “section
 19 1854(h)”.

20 (G) Section 1876(k)(4)(C) (42 U.S.C.
 21 1395mm(k)(4)(C)) is amended by inserting “(as
 22 in effect immediately before the enactment of the
 23 Prescription Drug and Medicare Improvements
 24 Act of 2003)” after “section 1851(e)(6)”.

1 (H) Section 1894(d) (42 U.S.C. 1395eee(d))
 2 is amended by adding at the end the following
 3 new paragraph:

4 “(3) APPLICATION OF PROVISIONS.—For pur-
 5 poses of paragraphs (1) and (2), the references to sec-
 6 tion 1853 and subsection (a)(2) of such section in
 7 such paragraphs shall be deemed to be references to
 8 those provisions as in effect immediately before the
 9 enactment of the Prescription Drug and Medicare Im-
 10 provements Act of 2003.”.

11 (2) CONFORMING MEDICARE TERMINOLOGY.—
 12 Title XVIII (42 U.S.C. 1395 et seq.), except for part
 13 C of such title (42 U.S.C. 1395w–21 et seq.), and title
 14 XIX (42 U.S.C. 1396 et seq.) are each amended by
 15 striking “Medicare+Choice” and inserting
 16 “MedicareAdvantage” each place it appears.

17 **SEC. 209. EFFECTIVE DATE.**

18 (a) IN GENERAL.—Except as provided in section
 19 208(d)(3) and subsection (b), the amendments made by this
 20 title shall apply with respect to plan years beginning on
 21 and after January 1, 2006.

22 (b) MEDICAREADVANTAGE MSA PLANS.—Notwith-
 23 standing any provision of this title, the Secretary shall
 24 apply the payment and other rules that apply with respect
 25 to an MSA plan described in section 1851(a)(2)(B) of the

1 *Social Security Act (42 U.S.C. 1395w–21(a)(2)(B)) as if*
 2 *this title had not been enacted.*

3 **SEC. 210. IMPROVEMENTS IN MEDICAREADVANTAGE**
 4 **BENCHMARK DETERMINATIONS.**

5 *(a) INCLUSION OF COSTS OF DOD AND VA MILITARY*
 6 *FACILITY SERVICES TO MEDICARE-ELIGIBLE BENE-*
 7 *FICIARIES IN CALCULATION OF MEDICAREADVANTAGE PAY-*
 8 *MENT RATES.—*

9 *(1) FOR PURPOSES OF CALCULATING*
 10 *MEDICARE+CHOICE PAYMENT RATES.—Section*
 11 *1853(c)(3) (42 U.S.C. 1395w–23(c)(3)), as amended*
 12 *by section 203, is amended—*

13 *(A) in subparagraph (A), by striking “sub-*
 14 *paragraph (B)” and inserting “subparagraphs*
 15 *(B) and (E)”;* and

16 *(B) by adding at the end the following new*
 17 *subparagraph:*

18 *“(E) INCLUSION OF COSTS OF DOD AND VA*
 19 *MILITARY FACILITY SERVICES TO MEDICARE-ELI-*
 20 *GIBLE BENEFICIARIES.—In determining the*
 21 *area-specific Medicare+Choice capitation rate*
 22 *under subparagraph (A) for a year (beginning*
 23 *with 2006), the annual per capita rate of pay-*
 24 *ment for 1997 determined under section*
 25 *1876(a)(1)(C) shall be adjusted to include in the*

1 *rate the Secretary’s estimate, on a per capita*
 2 *basis, of the amount of additional payments that*
 3 *would have been made in the area involved*
 4 *under this title if individuals entitled to benefits*
 5 *under this title had not received services from fa-*
 6 *cilities of the Department of Defense or the De-*
 7 *partment of Veterans Affairs.”.*

8 *(2) FOR PURPOSES OF CALCULATING LOCAL FEE-*
 9 *FOR-SERVICE RATES.—Section 1853(d)(5) (42 U.S.C.*
 10 *1395w–23(d)(5)), as amended by section 203, is*
 11 *amended—*

12 *(A) in subparagraph (A), by striking “sub-*
 13 *paragraph (B)” and inserting “subparagraphs*
 14 *(B) and (C)”;* and

15 *(B) by adding at the end the following new*
 16 *subparagraph:*

17 *“(C) INCLUSION OF COSTS OF DOD AND VA*
 18 *MILITARY FACILITY SERVICES TO MEDICARE-ELI-*
 19 *GIBLE BENEFICIARIES.—In determining the local*
 20 *fee-for-service rate under subparagraph (A) for a*
 21 *year (beginning with 2006), the annual per cap-*
 22 *ita rate of payment for 1997 determined under*
 23 *section 1876(a)(1)(C) shall be adjusted to include*
 24 *in the rate the Secretary’s estimate, on a per*
 25 *capita basis, of the amount of additional pay-*

1 ments that would have been made in the area in-
 2 volved under this title if individuals entitled to
 3 benefits under this title had not received services
 4 from facilities of the Department of Defense or
 5 the Department of Veterans Affairs.”.

6 (b) *EFFECTIVE DATE.*—The amendments made by this
 7 section shall apply with respect to plan years beginning on
 8 and after January 1, 2006.

9 ***Subtitle B—Preferred Provider***
 10 ***Organizations***

11 ***SEC. 211. ESTABLISHMENT OF MEDICAREADVANTAGE PRE-***
 12 ***FERRED PROVIDER PROGRAM OPTION.***

13 (a) *ESTABLISHMENT OF PREFERRED PROVIDER PRO-*
 14 *GRAM OPTION.*—Section 1851(a)(2) is amended by adding
 15 at the end the following new subparagraph:

16 “(D) *PREFERRED PROVIDER ORGANIZATION*
 17 *PLANS.*—A MedicareAdvantage preferred pro-
 18 vider organization plan under the program es-
 19 tablished under section 1858.”.

20 (b) *PROGRAM SPECIFICATIONS.*—Part C of title XVIII
 21 (42 U.S.C. 1395w–21 et seq.) is amended by inserting after
 22 section 1857 the following new section:

23 “*PREFERRED PROVIDER ORGANIZATIONS*

24 “*SEC. 1858. (a) ESTABLISHMENT OF PROGRAM.*—

25 “(1) *IN GENERAL.*—Beginning on January 1,
 26 2006, there is established a preferred provider pro-

1 *gram under which preferred provider organization*
 2 *plans offered by preferred provider organizations are*
 3 *offered to MedicareAdvantage eligible individuals in*
 4 *preferred provider regions.*

5 “(2) *DEFINITIONS.*—

6 “(A) *PREFERRED PROVIDER ORGANIZA-*
 7 *TION.*—The term ‘preferred provider organiza-
 8 *tion’ means an entity with a contract under sec-*
 9 *tion 1857 that meets the requirements of this sec-*
 10 *tion applicable with respect to preferred provider*
 11 *organizations.*

12 “(B) *PREFERRED PROVIDER ORGANIZATION*
 13 *PLAN.*—The term ‘preferred provider organiza-
 14 *tion plan’ means a MedicareAdvantage plan*
 15 *that—*

16 “(i) *has a network of providers that*
 17 *have agreed to a contractually specified re-*
 18 *imbursement for covered benefits with the*
 19 *organization offering the plan;*

20 “(ii) *provides for reimbursement for all*
 21 *covered benefits regardless of whether such*
 22 *benefits are provided within such network of*
 23 *providers; and*

24 “(iii) *is offered by a preferred provider*
 25 *organization.*

1 “(C) *PREFERRED PROVIDER REGION.*—*The*
2 *term ‘preferred provider region’ means—*

3 “(i) *a region established under para-*
4 *graph (3); and*

5 “(ii) *a region that consists of the entire*
6 *United States.*

7 “(3) *PREFERRED PROVIDER REGIONS.*—*For pur-*
8 *poses of this part the Secretary shall establish pre-*
9 *ferred provider regions as follows:*

10 “(A) *There shall be at least 10 regions.*

11 “(B) *Each region must include at least 1*
12 *State.*

13 “(C) *The Secretary may not divide States*
14 *so that portions of the State are in different re-*
15 *gions.*

16 “(D) *To the extent possible, the Secretary*
17 *shall include multistate metropolitan statistical*
18 *areas in a single region. The Secretary may di-*
19 *vide metropolitan statistical areas where it is*
20 *necessary to establish regions of such size and ge-*
21 *ography as to maximize the participation of pre-*
22 *ferred provider organization plans.*

23 “(E) *The Secretary may conform the pre-*
24 *ferred provider regions to the service areas estab-*
25 *lished under section 1860D–10.*

1 “(b) *ELIGIBILITY, ELECTION, AND ENROLLMENT; BEN-*
2 *EFITS AND BENEFICIARY PROTECTIONS.*—

3 “(1) *IN GENERAL.*—*Except as provided in the*
4 *succeeding provisions of this subsection, the provisions*
5 *of sections 1851 and 1852 that apply with respect to*
6 *coordinated care plans shall apply to preferred pro-*
7 *vider organization plans offered by a preferred pro-*
8 *vider organization.*

9 “(2) *SERVICE AREA.*—*The service area of a pre-*
10 *ferred provider organization plan shall be a preferred*
11 *provider region.*

12 “(3) *AVAILABILITY.*—*Each preferred provider or-*
13 *ganization plan must be offered to each*
14 *MedicareAdvantage eligible individual who resides in*
15 *the service area of the plan.*

16 “(4) *AUTHORITY TO PROHIBIT RISK SELEC-*
17 *TION.*—*The provisions of section 1852(a)(6) shall*
18 *apply to preferred provider organization plans.*

19 “(5) *ASSURING ACCESS TO SERVICES IN PRE-*
20 *FERRED PROVIDER ORGANIZATION PLANS.*—

21 “(A) *IN GENERAL.*—*In addition to any*
22 *other requirements under this section, in the case*
23 *of a preferred provider organization plan, the or-*
24 *ganization offering the plan must demonstrate to*
25 *the Secretary that the organization has sufficient*

1 *number and range of health care professionals*
 2 *and providers willing to provide services under*
 3 *the terms of the plan.*

4 “(B) *DETERMINATION OF SUFFICIENT AC-*
 5 *CESS.—The Secretary shall find that an organi-*
 6 *zation has met the requirement under subpara-*
 7 *graph (A) with respect to any category of health*
 8 *care professional or provider if, with respect to*
 9 *that category of provider the plan has contracts*
 10 *or agreements with a sufficient number and*
 11 *range of providers within such category to pro-*
 12 *vide covered services under the terms of the plan.*

13 “(C) *CONSTRUCTION.—Subparagraph (B)*
 14 *shall not be construed as restricting—*

15 “(i) *the persons from whom enrollees*
 16 *under such plan may obtain covered bene-*
 17 *fits; or*

18 “(ii) *the categories of licensed health*
 19 *professionals or providers from whom en-*
 20 *rollees under such a plan may obtain cov-*
 21 *ered benefits if the covered services are pro-*
 22 *vided to enrollees in a State where 25 per-*
 23 *cent or more of the population resides in*
 24 *health professional shortage areas des-*

1 *ignated pursuant to section 332 of the Pub-*
 2 *lic Health Service Act.*

3 “(c) *PAYMENTS TO PREFERRED PROVIDER ORGANIZA-*
 4 *TIONS.—*

5 “(1) *PAYMENTS TO ORGANIZATIONS.—*

6 “(A) *MONTHLY PAYMENTS.—*

7 “(i) *IN GENERAL.—Under a contract*
 8 *under section 1857 and subject to para-*
 9 *graph (5), subsection (e), and section*
 10 *1859(e)(4), the Secretary shall make, to*
 11 *each preferred provider organization, with*
 12 *respect to coverage of an individual for a*
 13 *month under this part in a preferred pro-*
 14 *vider region, separate monthly payments*
 15 *with respect to—*

16 “(I) *benefits under the original*
 17 *medicare fee-for-service program under*
 18 *parts A and B in accordance with*
 19 *paragraph (4); and*

20 “(II) *benefits under the voluntary*
 21 *prescription drug program under part*
 22 *D in accordance with section 1858A*
 23 *and the other provisions of this part.*

24 “(ii) *SPECIAL RULE FOR END-STAGE*
 25 *RENAL DISEASE.—The Secretary shall es-*

1 *tablish separate rates of payment applicable*
 2 *with respect to classes of individuals deter-*
 3 *mined to have end-stage renal disease and*
 4 *enrolled in a preferred provider organiza-*
 5 *tion plan under this clause that are similar*
 6 *to the separate rates of payment described*
 7 *in section 1853(a)(1)(B).*

8 *“(B) ADJUSTMENT TO REFLECT NUMBER OF*
 9 *ENROLLEES.—The Secretary may retroactively*
 10 *adjust the amount of payment under this para-*
 11 *graph in a manner that is similar to the manner*
 12 *in which payment amounts may be retroactively*
 13 *adjusted under section 1853(a)(2).*

14 *“(C) COMPREHENSIVE RISK ADJUSTMENT*
 15 *METHODOLOGY.—The Secretary shall apply the*
 16 *comprehensive risk adjustment methodology de-*
 17 *scribed in section 1853(a)(3)(B) to 100 percent*
 18 *of the amount of payments to plans under para-*
 19 *graph (4)(D)(ii).*

20 *“(D) ADJUSTMENT FOR SPENDING VARI-*
 21 *ATIONS WITHIN A REGION.—The Secretary shall*
 22 *establish a methodology for adjusting the amount*
 23 *of payments to plans under paragraph (4)(D)(ii)*
 24 *that achieves the same objective as the adjust-*
 25 *ment described in paragraph 1853(a)(2)(C).*

1 “(2) *ANNUAL CALCULATION OF BENCHMARK*
2 *AMOUNTS FOR PREFERRED PROVIDER REGIONS.*—*For*
3 *each year (beginning in 2006), the Secretary shall*
4 *calculate a benchmark amount for each preferred pro-*
5 *vider region for each month for such year with respect*
6 *to coverage of the benefits available under the original*
7 *medicare fee-for-service program option equal to the*
8 *average of each benchmark amount calculated under*
9 *section 1853(a)(4) for each MedicareAdvantage pay-*
10 *ment area for the year within such region, weighted*
11 *by the number of MedicareAdvantage eligible individ-*
12 *uals residing in each such payment area for the year.*

13 “(3) *ANNUAL ANNOUNCEMENT OF PAYMENT FAC-*
14 *TORS.*—

15 “(A) *ANNUAL ANNOUNCEMENT.*—*Beginning*
16 *in 2005, at the same time as the Secretary pub-*
17 *lishes the risk adjusters under section 1860D–11,*
18 *the Secretary shall annually announce (in a*
19 *manner intended to provide notice to interested*
20 *parties) the following payment factors:*

21 “(i) *The benchmark amount for each*
22 *preferred provider region (as calculated*
23 *under paragraph (2)(A)) for the year.*

24 “(ii) *The factors to be used for adjust-*
25 *ing payments described under—*

1 “(I) *the comprehensive risk ad-*
 2 *justment methodology described in*
 3 *paragraph (1)(C) with respect to each*
 4 *preferred provider region for the year;*
 5 *and*

6 “(II) *the methodology used for ad-*
 7 *justment for geographic variations*
 8 *within such region established under*
 9 *paragraph (1)(D).*

10 “(B) *ADVANCE NOTICE OF METHODO-*
 11 *LOGICAL CHANGES.—At least 45 days before*
 12 *making the announcement under subparagraph*
 13 *(A) for a year, the Secretary shall—*

14 “(i) *provide for notice to preferred pro-*
 15 *vider organizations of proposed changes to*
 16 *be made in the methodology from the meth-*
 17 *odology and assumptions used in the pre-*
 18 *vious announcement; and*

19 “(ii) *provide such organizations with*
 20 *an opportunity to comment on such pro-*
 21 *posed changes.*

22 “(C) *EXPLANATION OF ASSUMPTIONS.—In*
 23 *each announcement made under subparagraph*
 24 *(A), the Secretary shall include an explanation*
 25 *of the assumptions and changes in methodology*

1 *used in the announcement in sufficient detail so*
 2 *that preferred provider organizations can com-*
 3 *pute each payment factor described in such sub-*
 4 *paragraph.*

5 *“(4) SECRETARY’S DETERMINATION OF PAYMENT*
 6 *AMOUNT FOR BENEFITS UNDER THE ORIGINAL MEDI-*
 7 *CARE FEE-FOR-SERVICE PROGRAM.—The Secretary*
 8 *shall determine the payment amount for plans as fol-*
 9 *lows:*

10 *“(A) REVIEW OF PLAN BIDS.—The Sec-*
 11 *retary shall review each plan bid submitted*
 12 *under subsection (d)(1) for the coverage of bene-*
 13 *fits under the original medicare fee-for-service*
 14 *program option to ensure that such bids are con-*
 15 *sistent with the requirements under this part*
 16 *and are based on the assumptions described in*
 17 *section 1854(a)(2)(A)(iii) that the plan used*
 18 *with respect to numbers of enrolled individuals.*

19 *“(B) DETERMINATION OF PREFERRED PRO-*
 20 *VIDER REGIONAL BENCHMARK AMOUNTS.—The*
 21 *Secretary shall calculate a preferred provider re-*
 22 *gional benchmark amount for that plan for the*
 23 *benefits under the original medicare fee-for-serv-*
 24 *ice program option for each plan equal to the re-*
 25 *gional benchmark adjusted by using the assump-*

tions described in section 1854(a)(2)(A)(iii) that the plan used with respect to numbers of enrolled individuals.

“(C) *COMPARISON TO BENCHMARK.*—The Secretary shall determine the difference between each plan bid (as adjusted under subparagraph (A)) and the preferred provider regional benchmark amount (as determined under subparagraph (B)) for purposes of determining—

“(i) the payment amount under subparagraph (D); and

“(ii) the additional benefits required and MedicareAdvantage monthly basic beneficiary premiums.

“(D) *DETERMINATION OF PAYMENT AMOUNT.*—

“(i) *IN GENERAL.*—Subject to clause (ii), the Secretary shall determine the payment amount to a preferred provider organization for a preferred provider organization plan as follows:

“(I) *BIDS THAT EQUAL OR EXCEED THE BENCHMARK.*—In the case of a plan bid that equals or exceeds the preferred provider regional benchmark

1 *amount, the amount of each monthly*
 2 *payment to the organization with re-*
 3 *spect to each individual enrolled in a*
 4 *plan shall be the preferred provider re-*
 5 *gional benchmark amount.*

6 “(II) *BIDS BELOW THE BENCH-*
 7 *MARK.—In the case of a plan bid that*
 8 *is less than the preferred provider re-*
 9 *gional benchmark amount, the amount*
 10 *of each monthly payment to the orga-*
 11 *nization with respect to each indi-*
 12 *vidual enrolled in a plan shall be the*
 13 *preferred provider regional benchmark*
 14 *amount reduced by the amount of any*
 15 *premium reduction elected by the plan*
 16 *under section 1854(d)(1)(A)(i).*

17 “(ii) *APPLICATION OF ADJUSTMENT*
 18 *METHODOLOGIES.—The Secretary shall ad-*
 19 *just the amounts determined under subpara-*
 20 *graph (A) using the factors described in*
 21 *paragraph (3)(A)(ii).*

22 “(E) *FACTORS USED IN ADJUSTING BIDS*
 23 *AND BENCHMARKS FOR PREFERRED PROVIDER*
 24 *ORGANIZATIONS AND IN DETERMINING ENROLLEE*
 25 *PREMIUMS.—Subject to subparagraph (F), in*

1 *addition to the factors used to adjust payments*
 2 *to plans described in section 1853(d)(6), the Sec-*
 3 *retary shall use the adjustment for geographic*
 4 *variation within the region established under*
 5 *paragraph (1)(D).*

6 “(F) *ADJUSTMENT FOR NATIONAL COV-*
 7 *ERAGE DETERMINATIONS AND LEGISLATIVE*
 8 *CHANGES IN BENEFITS.*—*The Secretary shall*
 9 *provide for adjustments for national coverage de-*
 10 *terminations and legislative changes in benefits*
 11 *applicable with respect to preferred provider or-*
 12 *ganizations in the same manner as the Secretary*
 13 *provides for adjustments under section*
 14 *1853(d)(7).*

15 “(5) *PAYMENTS FROM TRUST FUND.*—*The pay-*
 16 *ment to a preferred provider organization under this*
 17 *section shall be made from the Federal Hospital In-*
 18 *surance Trust Fund and the Federal Supplementary*
 19 *Medical Insurance Trust Fund in a manner similar*
 20 *to the manner described in section 1853(g).*

21 “(6) *SPECIAL RULE FOR CERTAIN INPATIENT*
 22 *HOSPITAL STAYS.*—*Rules similar to the rules applica-*
 23 *ble under section 1853(h) shall apply with respect*
 24 *preferred provider organizations.*

1 “(7) *SPECIAL RULE FOR HOSPICE CARE.*—*Rules*
 2 *similar to the rules applicable under section 1853(i)*
 3 *shall apply with respect to preferred provider organi-*
 4 *zations.*

5 “(d) *SUBMISSION OF BIDS BY PPOS; PREMIUMS.*—

6 “(1) *SUBMISSION OF BIDS BY PREFERRED PRO-*
 7 *VIDER ORGANIZATIONS.*—

8 “(A) *IN GENERAL.*—*For the requirements*
 9 *on submissions by MedicareAdvantage preferred*
 10 *provider organization plans, see section*
 11 *1854(a)(1).*

12 “(B) *UNIFORM PREMIUMS.*—*Each bid*
 13 *amount submitted under subparagraph (A) for a*
 14 *preferred provider organization plan in a pre-*
 15 *ferred provider region may not vary among*
 16 *MedicareAdvantage eligible individuals residing*
 17 *in such preferred provider region.*

18 “(C) *APPLICATION OF FEHBP STANDARD;*
 19 *PROHIBITION ON PRICE GOUGING.*—*Each bid*
 20 *amount submitted under subparagraph (A) for a*
 21 *preferred provider organization plan must rea-*
 22 *sonably and equitably reflect the cost of benefits*
 23 *provided under that plan.*

24 “(D) *REVIEW.*—*The Secretary shall review*
 25 *the adjusted community rates (as defined in sec-*

tion 1854(g)(3)), the amounts of the MedicareAdvantage monthly basic premium and the MedicareAdvantage monthly beneficiary premium for enhanced medical benefits filed under this paragraph and shall approve or disapprove such rates and amounts so submitted. The Secretary shall review the actuarial assumptions and data used by the preferred provider organization with respect to such rates and amounts so submitted to determine the appropriateness of such assumptions and data.

“(E) *AUTHORITY TO LIMIT NUMBER OF PLANS IN A REGION.*—If there are bids for more than 3 preferred provider organization plans in a preferred provider region, the Secretary shall accept only the 3 lowest-cost credible bids for that region that meet or exceed the quality and minimum standards applicable under this section.

“(2) *MONTHLY PREMIUMS CHARGED.*—The amount of the monthly premium charged to an individual enrolled in a preferred provider organization plan offered by a preferred provider organization shall be equal to the sum of the following:

1 “(A) *The MedicareAdvantage monthly basic*
 2 *beneficiary premium, as defined in section*
 3 *1854(b)(2)(A) (if any).*

4 “(B) *The MedicareAdvantage monthly bene-*
 5 *ficiary premium for enhanced medical benefits,*
 6 *as defined in section 1854(b)(2)(C) (if any).*

7 “(C) *The MedicareAdvantage monthly obli-*
 8 *gation for qualified prescription drug coverage,*
 9 *as defined in section 1854(b)(2)(B) (if any).*

10 “(3) *DETERMINATION OF PREMIUM REDUCTIONS,*
 11 *REDUCED COST-SHARING, ADDITIONAL BENEFITS, AND*
 12 *BENEFICIARY PREMIUMS.—The rules for determining*
 13 *premium reductions, reduced cost-sharing, additional*
 14 *benefits, and beneficiary premiums under section*
 15 *1854(d) shall apply with respect to preferred provider*
 16 *organizations.*

17 “(4) *PROHIBITION OF SEGMENTING PREFERRED*
 18 *PROVIDER REGIONS.—The Secretary may not permit*
 19 *a preferred provider organization to elect to apply the*
 20 *provisions of this section uniformly to separate seg-*
 21 *ments of a preferred provider region (rather than uni-*
 22 *formly to an entire preferred provider region).*

23 “(e) *PORTION OF TOTAL PAYMENTS TO AN ORGANIZA-*
 24 *TION SUBJECT TO RISK FOR 2 YEARS.—*

1 “(1) *NOTIFICATION OF SPENDING UNDER THE*
2 *PLAN.*—

3 “(A) *IN GENERAL.*—*For 2007 and 2008, the*
4 *preferred provider organization offering a pre-*
5 *ferred provider organization plan shall notify the*
6 *Secretary of the total amount of costs that the or-*
7 *ganization incurred in providing benefits covered*
8 *under parts A and B of the original medicare*
9 *fee-for-service program for all enrollees under the*
10 *plan in the previous year.*

11 “(B) *CERTAIN EXPENSES NOT INCLUDED.*—
12 *The total amount of costs specified in subpara-*
13 *graph (A) may not include—*

14 “(i) *subject to subparagraph (C), ad-*
15 *ministrative expenses incurred in providing*
16 *the benefits described in such subparagraph;*
17 *or*

18 “(ii) *amounts expended on providing*
19 *enhanced medical benefits under section*
20 *1852(a)(3)(D).*

21 “(C) *ESTABLISHMENT OF ALLOWABLE AD-*
22 *MINISTRATIVE EXPENSES.*—*For purposes of ap-*
23 *plying subparagraph (B)(i), the administrative*
24 *expenses incurred in providing benefits described*
25 *in subparagraph (A) under a preferred provider*

1 *organization plan may not exceed an amount de-*
 2 *termined appropriate by the Administrator.*

3 “(2) *ADJUSTMENT OF PAYMENT.*—

4 “(A) *NO ADJUSTMENT IF COSTS WITHIN*
 5 *RISK CORRIDOR.*—*If the total amount of costs*
 6 *specified in paragraph (1)(A) for the plan for*
 7 *the year are not more than the first threshold*
 8 *upper limit of the risk corridor (specified in*
 9 *paragraph (3)(A)(iii)) and are not less than the*
 10 *first threshold lower limit of the risk corridor*
 11 *(specified in paragraph (3)(A)(i)) for the plan*
 12 *for the year, then no additional payments shall*
 13 *be made by the Secretary and no reduced pay-*
 14 *ments shall be made to the preferred provider or-*
 15 *ganization offering the plan.*

16 “(B) *INCREASE IN PAYMENT IF COSTS*
 17 *ABOVE UPPER LIMIT OF RISK CORRIDOR.*—

18 “(i) *IN GENERAL.*—*If the total amount*
 19 *of costs specified in paragraph (1)(A) for*
 20 *the plan for the year are more than the first*
 21 *threshold upper limit of the risk corridor for*
 22 *the plan for the year, then the Secretary*
 23 *shall increase the total of the monthly pay-*
 24 *ments made to the preferred provider orga-*
 25 *nization offering the plan for the year*

1 under subsection (c)(1)(A) by an amount
2 equal to the sum of—

3 “(I) 50 percent of the amount of
4 such total costs which are more than
5 such first threshold upper limit of the
6 risk corridor and not more than the
7 second threshold upper limit of the risk
8 corridor for the plan for the year (as
9 specified under paragraph (3)(A)(iv));
10 and

11 “(II) 90 percent of the amount of
12 such total costs which are more than
13 such second threshold upper limit of
14 the risk corridor.

15 “(C) *REDUCTION IN PAYMENT IF COSTS*
16 *BELOW LOWER LIMIT OF RISK CORRIDOR.*—If the
17 total amount of costs specified in paragraph
18 (1)(A) for the plan for the year are less than the
19 first threshold lower limit of the risk corridor for
20 the plan for the year, then the Secretary shall re-
21 duce the total of the monthly payments made to
22 the preferred provider organization offering the
23 plan for the year under subsection (c)(1)(A) by
24 an amount (or otherwise recover from the plan
25 an amount) equal to—

1 “(i) 50 percent of the amount of such
 2 total costs which are less than such first
 3 threshold lower limit of the risk corridor
 4 and not less than the second threshold lower
 5 limit of the risk corridor for the plan for the
 6 year (as specified under paragraph
 7 (3)(A)(ii)); and

8 “(ii) 90 percent of the amount of such
 9 total costs which are less than such second
 10 threshold lower limit of the risk corridor.

11 “(3) ESTABLISHMENT OF RISK CORRIDORS.—

12 “(A) IN GENERAL.—For 2006 and 2007, the
 13 Secretary shall establish a risk corridor for each
 14 preferred provider organization plan. The risk
 15 corridor for a plan for a year shall be equal to
 16 a range as follows:

17 “(i) FIRST THRESHOLD LOWER
 18 LIMIT.—The first threshold lower limit of
 19 such corridor shall be equal to—

20 “(I) the target amount described
 21 in subparagraph (B) for the plan;
 22 minus

23 “(II) an amount equal to 5 per-
 24 cent of such target amount.

1 “(ii) *SECOND THRESHOLD LOWER*
 2 *LIMIT.—The second threshold lower limit of*
 3 *such corridor shall be equal to—*

4 “(I) *the target amount described*
 5 *in subparagraph (B) for the plan;*
 6 *minus*

7 “(II) *an amount equal to 10 per-*
 8 *cent of such target amount.*

9 “(iii) *FIRST THRESHOLD UPPER*
 10 *LIMIT.—The first threshold upper limit of*
 11 *such corridor shall be equal to the sum of—*

12 “(I) *such target amount; and*

13 “(II) *the amount described in*
 14 *clause (i)(II).*

15 “(iv) *SECOND THRESHOLD UPPER*
 16 *LIMIT.—The second threshold upper limit of*
 17 *such corridor shall be equal to the sum of—*

18 “(I) *such target amount; and*

19 “(II) *the amount described in*
 20 *clause (ii)(II).*

21 “(B) *TARGET AMOUNT DESCRIBED.—The*
 22 *target amount described in this paragraph is,*
 23 *with respect to a preferred provider organization*
 24 *plan offered by a preferred provider organization*
 25 *in a year, an amount equal to the sum of—*

1 “(i) the total monthly payments made
2 to the organization for enrollees in the plan
3 for the year under subsection (c)(1)(A); and

4 “(ii) the total MedicareAdvantage basic
5 beneficiary premiums collected for such en-
6 rollees for the year under subsection
7 (d)(2)(A).

8 “(4) PLANS AT RISK FOR ENTIRE AMOUNT OF
9 ENHANCED MEDICAL BENEFITS.—A preferred provider
10 organization that offers a preferred provider organi-
11 zation plan that provides enhanced medial benefits
12 under section 1852(a)(3)(D) shall be at full financial
13 risk for the provision of such benefits.

14 “(5) NO EFFECT ON ELIGIBLE BENEFICIARIES.—
15 No change in payments made by reason of this sub-
16 section shall affect the amount of the
17 MedicareAdvantage basic beneficiary premium that a
18 beneficiary is otherwise required to pay under the
19 plan for the year under subsection (d)(2)(A).

20 “(6) DISCLOSURE OF INFORMATION.—The provi-
21 sions of section 1860D–16(b)(7), including subpara-
22 graph (B) of such section, shall apply to a preferred
23 provider organization and a preferred provider orga-
24 nization plan in the same manner as such provisions

1 *apply to an eligible entity and a Medicare Prescrip-*
 2 *tion Drug plan under part D.*

3 “(f) *ORGANIZATIONAL AND FINANCIAL REQUIREMENTS*
 4 *FOR PREFERRED PROVIDER ORGANIZATIONS.*—A preferred
 5 *provider organization shall be organized and licensed under*
 6 *State law as a risk-bearing entity eligible to offer health*
 7 *insurance or health benefits coverage in each State within*
 8 *the preferred provider region in which it offers a preferred*
 9 *provider organization plan.*

10 “(g) *INAPPLICABILITY OF PROVIDER-SPONSORED OR-*
 11 *GANIZATION SOLVENCY STANDARDS.*—The requirements of
 12 *section 1856 shall not apply with respect to preferred pro-*
 13 *vider organizations.*

14 “(h) *CONTRACTS WITH PREFERRED PROVIDER ORGA-*
 15 *NIZATIONS.*—The provisions of section 1857 shall apply to
 16 *a preferred provider organization plan offered by a pre-*
 17 *ferred provider organization under this section.”.*

18 (c) *PREFERRED PROVIDER TERMINOLOGY DE-*
 19 *FINED.*—Section 1859(a) is amended by adding at the end
 20 *the following new paragraph:*

21 “(3) *PREFERRED PROVIDER ORGANIZATION; PRE-*
 22 *FERRED PROVIDER ORGANIZATION PLAN; PREFERRED*
 23 *PROVIDER REGION.*—The terms ‘preferred provider or-
 24 *ganization’, ‘preferred provider organization plan’,*

1 and ‘preferred provider region’ have the meaning
2 given such terms in section 1858(a)(2).”.

3 ***Subtitle C—Other Managed Care*** 4 ***Reforms***

5 ***SEC. 221. EXTENSION OF REASONABLE COST CONTRACTS.***

6 (a) *FIVE-YEAR EXTENSION.*—Section 1876(h)(5)(C)
7 (42 U.S.C. 1395mm(h)(5)(C)) is amended by striking
8 “2004” and inserting “2009”.

9 (b) *APPLICATION OF CERTAIN MEDICARE+CHOICE*
10 *REQUIREMENTS TO COST CONTRACTS EXTENDED OR RE-*
11 *NEWED AFTER 2003.*—Section 1876(h) (42 U.S.C.
12 1395mm(h)(5)), as amended by subsection (a), is
13 amended—

14 (1) by redesignating paragraph (5) as para-
15 graph (6); and

16 (2) by inserting after paragraph (4) the fol-
17 lowing new paragraph:

18 “(5) Any reasonable cost reimbursement contract with
19 an eligible organization under this subsection that is ex-
20 tended or renewed on or after the date of enactment of the
21 Prescription Drug and Medicare Improvements Act of 2003
22 for plan years beginning on or after January 1, 2004, shall
23 provide that the following provisions of the
24 Medicare+Choice program under part C (and, on and after
25 January 1, 2006, the provisions of the MedicareAdvantage

1 *program under such part) shall apply to such organization*
 2 *and such contract in a substantially similar manner as*
 3 *such provisions apply to Medicare+Choice organizations*
 4 *and Medicare+Choice plans (or, on and after January 1,*
 5 *2006, MedicareAdvantage organizations and*
 6 *MedicareAdvantage plans, respectively) under such part:*

7 “(A) Paragraph (1) of section 1852(e) (relating
 8 to the requirement of having an ongoing quality as-
 9 surance program) and paragraph (2)(B) of such sec-
 10 tion (relating to the required elements for such a pro-
 11 gram).

12 “(B) Section 1852(j)(4) (relating to limitations
 13 on physician incentive plans).

14 “(C) Section 1854(c) (relating to the requirement
 15 of uniform premiums among individuals enrolled in
 16 the plan).

17 “(D) Section 1854(g), or, on and after January
 18 1, 2006, section 1854(h) (relating to restrictions on
 19 imposition of premium taxes with respect to pay-
 20 ments to organizations).

21 “(E) Section 1856(b) (regarding compliance
 22 with the standards established by regulation pursuant
 23 to such section, including the provisions of paragraph
 24 (3) of such section relating to relation to State laws).

1 “(F) Section 1852(a)(3)(A) (regarding the au-
 2 thority of organizations to include supplemental
 3 health care benefits and, on and after January 1,
 4 2006, enhanced medical benefits under the plan sub-
 5 ject to the approval of the Secretary).

6 “(G) The provisions of part C relating to
 7 timelines for benefit filings, contract renewal, and
 8 beneficiary notification.

9 “(H) Section 1854(e), or, on and after January
 10 1, 2006, section 1854(f) (relating to proposed cost-
 11 sharing under the contract being subject to review by
 12 the Secretary).”.

13 (c) *PERMITTING DEDICATED GROUP PRACTICE*
 14 *HEALTH MAINTENANCE ORGANIZATIONS TO PARTICIPATE*
 15 *IN THE MEDICARE COST CONTRACT PROGRAM.*—Section
 16 1876(h)(6) of the Social Security Act (42 U.S.C.
 17 1395mm(h)(6)), as redesignated and amended by sub-
 18 sections (a) and (b), is amended—

19 (1) in subparagraph (A), by striking “After the
 20 date of the enactment” and inserting “Except as pro-
 21 vided in subparagraph (C), after the date of the en-
 22 actment”;

23 (2) in subparagraph (B), by striking “subpara-
 24 graph (C)” and inserting “subparagraph (D)”;

1 (3) by redesignating subparagraph (C) as sub-
2 paragraph (D); and

3 (4) by inserting after subparagraph (B), the fol-
4 lowing new subparagraph:

5 “(C) Subject to paragraph (5) and subparagraph (D),
6 the Secretary shall approve an application to enter into a
7 reasonable cost contract under this section if—

8 “(i) the application is submitted to the Secretary
9 by a health maintenance organization (as defined in
10 section 1301(a) of the Public Health Service Act)
11 that, as of January 1, 2004, and except as provided
12 in section 1301(b)(3)(B) of such Act, provides at least
13 85 percent of the services of a physician which are
14 provided as basic health services through a medical
15 group (or groups), as defined in section 1302(4) of
16 such Act; and

17 “(ii) the Secretary determines that the organiza-
18 tion meets the requirements applicable to such organi-
19 zations and contracts under this section.”.

20 **SEC. 222. SPECIALIZED MEDICARE+CHOICE PLANS FOR SPE-**
21 **CIAL NEEDS BENEFICIARIES.**

22 (a) *TREATMENT AS COORDINATED CARE PLAN.*—Sec-
23 tion 1851(a)(2)(A) (42 U.S.C. 1395w-21(a)(2)(A)) is
24 amended by adding at the end the following new sentence:
25 “Specialized Medicare+Choice plans for special needs bene-

1 *ficiaries (as defined in section 1859(b)(4)) may be any type*
 2 *of coordinated care plan.”.*

3 *(b) SPECIALIZED MEDICARE+CHOICE PLAN FOR SPE-*
 4 *CIAL NEEDS BENEFICIARIES DEFINED.—Section 1859(b)*
 5 *(42 U.S.C. 1395w–28(b)) is amended by adding at the end*
 6 *the following new paragraph:*

7 “(4) *SPECIALIZED MEDICARE+CHOICE PLANS*
 8 *FOR SPECIAL NEEDS BENEFICIARIES.—*

9 “(A) *IN GENERAL.—The term ‘specialized*
 10 *Medicare+Choice plans for special needs bene-*
 11 *ficiaries’ means a Medicare+Choice plan that—*

12 “(i) *exclusively serves special needs*
 13 *beneficiaries (as defined in subparagraph*
 14 *(B)), or*

15 “(ii) *to the extent provided in regula-*
 16 *tions prescribed by the Secretary, dispropor-*
 17 *tionately serves such special needs bene-*
 18 *ficiaries, frail elderly medicare bene-*
 19 *ficiaries, or both.*

20 “(B) *SPECIAL NEEDS BENEFICIARY.—The*
 21 *term ‘special needs beneficiary’ means a*
 22 *Medicare+Choice eligible individual who—*

23 “(i) *is institutionalized (as defined by*
 24 *the Secretary);*

1 “(ii) is entitled to medical assistance
2 under a State plan under title XIX; or

3 “(iii) meets such requirements as the
4 Secretary may determine would benefit
5 from enrollment in such a specialized
6 Medicare+Choice plan described in sub-
7 paragraph (A) for individuals with severe
8 or disabling chronic conditions.”.

9 (c) *RESTRICTION ON ENROLLMENT PERMITTED.*—Sec-
10 tion 1859 (42 U.S.C. 1395w–28) is amended by adding at
11 the end the following new subsection:

12 “(f) *RESTRICTION ON ENROLLMENT FOR SPECIALIZED*
13 *MEDICARE+CHOICE PLANS FOR SPECIAL NEEDS BENE-*
14 *FICIARIES.*—In the case of a specialized Medicare+Choice
15 plan (as defined in subsection (b)(4)), notwithstanding any
16 other provision of this part and in accordance with regula-
17 tions of the Secretary and for periods before January 1,
18 2008, the plan may restrict the enrollment of individuals
19 under the plan to individuals who are within 1 or more
20 classes of special needs beneficiaries.”.

21 (d) *REPORT TO CONGRESS.*—Not later than December
22 31, 2006, the Secretary shall submit to Congress a report
23 that assesses the impact of specialized Medicare+Choice
24 plans for special needs beneficiaries on the cost and quality
25 of services provided to enrollees. Such report shall include

1 *an assessment of the costs and savings to the medicare pro-*
 2 *gram as a result of amendments made by subsections (a),*
 3 *(b), and (c).*

4 *(e) EFFECTIVE DATES.—*

5 *(1) IN GENERAL.—The amendments made by*
 6 *subsections (a), (b), and (c) shall take effect on the*
 7 *date of enactment of this Act.*

8 *(2) DEADLINE FOR ISSUANCE OF REQUIREMENTS*
 9 *FOR SPECIAL NEEDS BENEFICIARIES; TRANSITION.—*
 10 *No later than 1 year after the date of enactment of*
 11 *this Act, the Secretary shall issue final regulations to*
 12 *establish requirements for special needs beneficiaries*
 13 *under section 1859(b)(4)(B)(iii) of the Social Secu-*
 14 *urity Act, as added by subsection (b).*

15 **SEC. 223. PAYMENT BY PACE PROVIDERS FOR MEDICARE**
 16 **AND MEDICAID SERVICES FURNISHED BY**
 17 **NONCONTRACT PROVIDERS.**

18 *(a) MEDICARE SERVICES.—*

19 *(1) MEDICARE SERVICES FURNISHED BY PRO-*
 20 *VIDERS OF SERVICES.—Section 1866(a)(1)(O) (42*
 21 *U.S.C. 1395cc(a)(1)(O)) is amended—*

22 *(A) by striking “part C or” and inserting*
 23 *“part C, with a PACE provider under section*
 24 *1894 or 1934, or”;*

25 *(B) by striking “(i)”;*

1 (C) by striking “and (ii)”; and

2 (D) by striking “members of the organiza-
3 tion” and inserting “members of the organiza-
4 tion or PACE program eligible individuals en-
5 rolled with the PACE provider,”.

6 (2) *MEDICARE SERVICES FURNISHED BY PHYSI-
7 CIANS AND OTHER ENTITIES.*—Section 1894(b) (42
8 U.S.C. 1395eee(b)) is amended by adding at the end
9 the following new paragraphs:

10 “(3) *TREATMENT OF MEDICARE SERVICES FUR-
11 NISHED BY NONCONTRACT PHYSICIANS AND OTHER
12 ENTITIES.*—

13 “(A) *APPLICATION OF MEDICARE+CHOICE
14 REQUIREMENT WITH RESPECT TO MEDICARE
15 SERVICES FURNISHED BY NONCONTRACT PHYSI-
16 CIANS AND OTHER ENTITIES.*—Section
17 1852(k)(1) (relating to limitations on balance
18 billing against Medicare+Choice organizations
19 for noncontract physicians and other entities
20 with respect to services covered under this title)
21 shall apply to PACE providers, PACE program
22 eligible individuals enrolled with such PACE
23 providers, and physicians and other entities that
24 do not have a contract establishing payment
25 amounts for services furnished to such an indi-

vidual in the same manner as such section applies to Medicare+Choice organizations, individuals enrolled with such organizations, and physicians and other entities referred to in such section.

“(B) REFERENCE TO RELATED PROVISION FOR NONCONTRACT PROVIDERS OF SERVICES.—For the provision relating to limitations on balance billing against PACE providers for services covered under this title furnished by noncontract providers of services, see section 1866(a)(1)(O).

“(4) REFERENCE TO RELATED PROVISION FOR SERVICES COVERED UNDER TITLE XIX BUT NOT UNDER THIS TITLE.—For provisions relating to limitations on payments to providers participating under the State plan under title XIX that do not have a contract with a PACE provider establishing payment amounts for services covered under such plan (but not under this title) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(66).”.

(b) MEDICAID SERVICES.—

(1) REQUIREMENT UNDER STATE PLAN.—Section 1902(a) (42 U.S.C. 1396a(a)) is amended—

1 (A) in paragraph (64), by striking “and”
2 at the end;

3 (B) in paragraph (65), by striking the pe-
4 riod at the end and inserting “; and”; and

5 (C) by inserting after paragraph (65) the
6 following new paragraph:

7 “(66) provide, with respect to services cov-
8 ered under the State plan (but not under title
9 XVIII) that are furnished to a PACE program
10 eligible individual enrolled with a PACE pro-
11 vider by a provider participating under the
12 State plan that does not have a contract with the
13 PACE provider that establishes payment
14 amounts for such services, that such partici-
15 pating provider may not require the PACE pro-
16 vider to pay the participating provider an
17 amount greater than the amount that would oth-
18 erwise be payable for the service to the partici-
19 pating provider under the State plan for the
20 State where the PACE provider is located (in ac-
21 cordance with regulations issued by the Sec-
22 retary).”.

23 (2) *REFERENCE IN MEDICAID STATUTE.*—Section
24 1934(b) (42 U.S.C. 1396u–4(b)) is amended by add-
25 ing at the end the following new paragraphs:

1 “(3) *TREATMENT OF MEDICARE SERVICES FUR-*
2 *NISHED BY NONCONTRACT PHYSICIANS AND OTHER*
3 *ENTITIES.*—

4 “(A) *APPLICATION OF MEDICARE+CHOICE*
5 *REQUIREMENT WITH RESPECT TO MEDICARE*
6 *SERVICES FURNISHED BY NONCONTRACT PHYSI-*
7 *CANS AND OTHER ENTITIES.*—*Section*
8 *1852(k)(1) (relating to limitations on balance*
9 *billing against Medicare+Choice organizations*
10 *for noncontract physicians and other entities*
11 *with respect to services covered under title*
12 *XVIII) shall apply to PACE providers, PACE*
13 *program eligible individuals enrolled with such*
14 *PACE providers, and physicians and other enti-*
15 *ties that do not have a contract establishing pay-*
16 *ment amounts for services furnished to such an*
17 *individual in the same manner as such section*
18 *applies to Medicare+Choice organizations, indi-*
19 *viduals enrolled with such organizations, and*
20 *physicians and other entities referred to in such*
21 *section.*

22 “(B) *REFERENCE TO RELATED PROVISION*
23 *FOR NONCONTRACT PROVIDERS OF SERVICES.*—
24 *For the provision relating to limitations on bal-*
25 *ance billing against PACE providers for services*

covered under title XVIII furnished by noncontract providers of services, see section 1866(a)(1)(O).

“(4) *REFERENCE TO RELATED PROVISION FOR SERVICES COVERED UNDER THIS TITLE BUT NOT UNDER TITLE XVIII.*—For provisions relating to limitations on payments to providers participating under the State plan under this title that do not have a contract with a PACE provider establishing payment amounts for services covered under such plan (but not under title XVIII) when such services are furnished to enrollees of that PACE provider, see section 1902(a)(66).”.

(c) *EFFECTIVE DATE.*—The amendments made by this section shall apply to services furnished on or after January 1, 2004.

SEC. 224. INSTITUTE OF MEDICINE EVALUATION AND REPORT ON HEALTH CARE PERFORMANCE MEASURES.

(a) *EVALUATION.*—

(1) *IN GENERAL.*—Not later than the date that is 2 months after the date of enactment of this Act, the Secretary of Health and Human Services shall enter into an arrangement under which the Institute

1 *of Medicine of the National Academy of Sciences (in*
2 *this section referred to as the “Institute”)* shall con-
3 *duct an evaluation of leading health care performance*
4 *measures and options to implement policies that align*
5 *performance with payment under the medicare pro-*
6 *gram under title XVIII of the Social Security Act (42*
7 *U.S.C. 1395 et seq.).*

8 (2) *SPECIFIC MATTERS EVALUATED.—In con-*
9 *ducting the evaluation under paragraph (1), the In-*
10 *stitute shall—*

11 (A) *catalogue, review, and evaluate the va-*
12 *lidity of leading health care performance meas-*
13 *ures;*

14 (B) *catalogue and evaluate the success and*
15 *utility of alternative performance incentive pro-*
16 *grams in public or private sector settings; and*

17 (C) *identify and prioritize options to imple-*
18 *ment policies that align performance with pay-*
19 *ment under the medicare program that*
20 *indicate—*

21 (i) *the performance measurement set to*
22 *be used and how that measurement set will*
23 *be updated;*

24 (ii) *the payment policy that will re-*
25 *ward performance; and*

1 (iii) the key implementation issues
 2 (such as data and information technology
 3 requirements) that must be addressed.

4 (3) SCOPE OF HEALTH CARE PERFORMANCE
 5 MEASURES.—The health care performance measures
 6 described in paragraph (2)(A) shall encompass a va-
 7 riety of perspectives, including physicians, hospitals,
 8 health plans, purchasers, and consumers.

9 (4) CONSULTATION WITH MEDPAC.—In evalu-
 10 ating the matters described in paragraph (2)(C), the
 11 Institute shall consult with the Medicare Payment
 12 Advisory Commission established under section 1805
 13 of the Social Security Act (42 U.S.C. 1395b–6).

14 (b) REPORT.—Not later than the date that is 18
 15 months after the date of enactment of this Act, the Institute
 16 shall submit to the Secretary of Health and Human Serv-
 17 ices, the Committees on Ways and Means and Energy and
 18 Commerce of the House of Representatives, and the Com-
 19 mittee on Finance of the Senate a report on the evaluation
 20 conducted under subsection (a)(1) describing the findings
 21 of such evaluation and recommendations for an overall
 22 strategy and approach for aligning payment with perform-
 23 ance in the original medicare fee-for-service program under
 24 parts A and B of title XVIII of the Social Security Act,

1 *the Medicare+Choice program under part C of such title,*
 2 *and any other programs under such title XVIII.*

3 (c) *AUTHORIZATION OF APPROPRIATIONS.—There are*
 4 *authorized to be appropriated \$1,000,000 for purposes of*
 5 *conducting the evaluation and preparing the report re-*
 6 *quired by this section.*

7 **SEC. 225. EXPANDING THE WORK OF MEDICARE QUALITY**
 8 **IMPROVEMENT ORGANIZATIONS TO INCLUDE**
 9 **PARTS C AND D.**

10 (a) *APPLICATION TO MEDICARE MANAGED CARE AND*
 11 *PRESCRIPTION DRUG COVERAGE.—Section 1154(a)(1) (42*
 12 *U.S.C. 1320c–3(a)(1)) is amended by inserting “,*
 13 *Medicare+Choice organizations and MedicareAdvantage*
 14 *organizations under part C, and prescription drug card*
 15 *sponsors and eligible entities under part D” after “under*
 16 *section 1876”.*

17 (b) *PRESCRIPTION DRUG THERAPY QUALITY IM-*
 18 *PROVEMENT.—Section 1154(a) (42 U.S.C. 1320c–3(a)) is*
 19 *amended by adding at the end the following new paragraph:*

20 “(17) *The organization shall execute its respon-*
 21 *sibilities under subparagraphs (A) and (B) of para-*
 22 *graph (1) by offering to providers, practitioners, pre-*
 23 *scription drug card sponsors and eligible entities*
 24 *under part D, and Medicare+Choice and*
 25 *MedicareAdvantage plans under part C quality im-*

7 **SEC. 226. EXTENSION OF DEMONSTRATION FOR ESRD MAN-**
8 **AGED CARE.**

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1 ***Subtitle D—Evaluation of Alter-***
 2 ***native Payment and Delivery***
 3 ***Systems***

4 ***SEC. 231. ESTABLISHMENT OF ALTERNATIVE PAYMENT SYS-***
 5 ***TEM FOR PREFERRED PROVIDER ORGANIZA-***
 6 ***TIONS IN HIGHLY COMPETITIVE REGIONS.***

7 *(a) ESTABLISHMENT OF ALTERNATIVE PAYMENT SYS-*
 8 *TEM FOR PREFERRED PROVIDER ORGANIZATIONS IN HIGH-*
 9 *LY COMPETITIVE REGIONS.—Section 1858 (as added by sec-*
 10 *tion 211(b)) is amended by adding at the end the following*
 11 *new subsection:*

12 *“(i) ALTERNATIVE PAYMENT METHODOLOGY FOR*
 13 *HIGHLY COMPETITIVE REGIONS.—*

14 *“(1) ANNUAL DETERMINATION AND DESIGNA-*
 15 *TION.—*

16 *“(A) IN 2008.—In 2008, prior to the date on*
 17 *which the Secretary expects to publish the risk*
 18 *adjusters under section 1860D–11, the Secretary*
 19 *shall designate a limited number (but in no case*
 20 *fewer than 1) of preferred provider regions (other*
 21 *than the region described in subsection*
 22 *(a)(2)(C)(ii)) as highly competitive regions.*

23 *“(B) SUBSEQUENT YEARS.—For each year*
 24 *(beginning with 2009) the Secretary may des-*
 25 *ignate a limited number of preferred provider re-*

gions (other than the region described in subsection (a)(2)(C)(ii)) as highly competitive regions in addition to any region designated as a highly competitive region under subparagraph (A).

“(C) *CONSIDERATIONS.*—In determining which preferred provider regions to designate as highly competitive regions under subparagraph (A) or (B), the Secretary shall consider the following:

“(i) *Whether the application of this subsection to the preferred provider region would enhance the participation of preferred provider organization plans in that region.*

“(ii) *Whether the Secretary anticipates that there is likely to be at least 3 bids submitted under subsection (d)(1) with respect to the preferred provider region if the Secretary designates such region as a highly competitive region under subparagraph (A) or (B).*

“(iii) *Whether the Secretary expects that MedicareAdvantage eligible individuals will elect preferred provider organization*

1 *plans in the preferred provider region if the*
 2 *region is designated as a highly competitive*
 3 *region under subparagraph (A) or (B).*

4 *“(iv) Whether the designation of the*
 5 *preferred provider region as a highly com-*
 6 *petitive region will permit compliance with*
 7 *the limitation described in paragraph (5).*

8 *In considering the matters described in clauses*
 9 *(i) through (iv), the Secretary shall give special*
 10 *consideration to preferred provider regions where*
 11 *no bids were submitted under subsection (d)(1)*
 12 *for the previous year.*

13 *“(2) EFFECT OF DESIGNATION.—If a preferred*
 14 *provider region is designated as a highly competitive*
 15 *region under subparagraph (A) or (B) of paragraph*
 16 *(1)—*

17 *“(A) the provisions of this subsection shall*
 18 *apply to such region and shall supersede the pro-*
 19 *visions of this part relating to benchmarks for*
 20 *preferred provider regions; and*

21 *“(B) such region shall continue to be a*
 22 *highly competitive region until such designation*
 23 *is rescinded pursuant to paragraph (5)(B)(ii).*

24 *“(3) SUBMISSION OF BIDS.—*

1 “(A) *IN GENERAL*.—Notwithstanding sub-
 2 section (d)(1), for purposes of applying section
 3 1854(a)(2)(A)(i), the plan bid for a highly com-
 4 petitive region shall consist of a dollar amount
 5 that represents the total amount that the plan is
 6 willing to accept (not taking into account the
 7 application of the comprehensive risk adjustment
 8 methodology under section 1853(a)(3)) for pro-
 9 viding coverage of only the benefits described in
 10 section 1852(a)(1)(A) to an individual enrolled
 11 in the plan that resides in the service area of the
 12 plan for a month.

13 “(B) *CONSTRUCTION*.—Nothing in subpara-
 14 graph (A) shall be construed as permitting a
 15 preferred provider organization plan not to pro-
 16 vide coverage for the benefits described in section
 17 1852(a)(1)(C).

18 “(4) *PAYMENTS TO PREFERRED PROVIDER ORGA-*
 19 *NIZATIONS IN HIGHLY COMPETITIVE AREAS*.—With re-
 20 spect to highly competitive regions, the following rules
 21 shall apply:

22 “(A) *IN GENERAL*.—Notwithstanding sub-
 23 section (c), of the plans described in subsection
 24 (d)(1)(E), the Secretary shall substitute the sec-

1 *ond lowest bid for the benchmark applicable*
 2 *under subsection (c)(4).*

3 “(B) *IF THERE ARE FEWER THAN THREE*
 4 *BIDS.—Notwithstanding subsection (c), if there*
 5 *are fewer than 3 bids in a highly competitive re-*
 6 *gion for a year, the Secretary shall substitute the*
 7 *lowest bid for the benchmark applicable under*
 8 *subsection (c)(4).*

9 “(5) *FUNDING LIMITATION.—*

10 “(A) *IN GENERAL.—*

11 “(i) *IN GENERAL.—The total amount*
 12 *expended as a result of the application of*
 13 *this subsection during the period or year, as*
 14 *applicable, may not exceed the applicable*
 15 *amount (as defined in clause (ii)).*

16 “(ii) *APPLICABLE AMOUNT DEFINED.—*
 17 *In this paragraph, the term ‘applicable*
 18 *amount’ means—*

19 “(I) *for the period beginning on*
 20 *January 1, 2009, and ending on Sep-*
 21 *tember 30, 2013, the total amount that*
 22 *would have been expended under this*
 23 *title during the period if this sub-*
 24 *section had not been enacted plus*
 25 *\$6,000,000,000; and*

1 “(II) for fiscal year 2014 and any
 2 subsequent fiscal year, the total
 3 amount that would have been expended
 4 under this title during the year if this
 5 subsection had not been enacted.

6 “(B) APPLICATION OF LIMITATION.—If the
 7 Secretary determines that the application of this
 8 subsection will cause expenditures to exceed the
 9 applicable amount, the Secretary shall—

10 “(i) take appropriate steps to stay
 11 within the applicable amount, including
 12 through providing limitations on enroll-
 13 ment; or

14 “(ii) rescind the designation under
 15 subparagraph (A) or (B) of paragraph (1)
 16 of 1 or more preferred provider regions as
 17 highly competitive regions.

18 “(C) TRANSITION.—If the Secretary re-
 19 scinds a designation under subparagraph (A) or
 20 (B) of paragraph (1) pursuant to subparagraph
 21 (B)(ii) with respect to a preferred provider re-
 22 gion, the Secretary shall provide for an appro-
 23 priate transition from the payment system ap-
 24 plicable under this subsection to the payment
 25 system described in the other provisions of this

1 *section in that region. Any amount expended by*
 2 *reason of the preceding sentence shall be consid-*
 3 *ered to be part of the total amount expended as*
 4 *a result of the application of this subsection for*
 5 *purposes of applying the limitation under sub-*
 6 *paragraph (A).*

7 “(D) *APPLICATION.—Notwithstanding*
 8 *paragraph (1)(B), on or after January 1 of the*
 9 *year in which the fiscal year described in sub-*
 10 *paragraph (A)(ii)(II) begins, the Secretary may*
 11 *designate appropriate regions under such para-*
 12 *graph.*

13 “(6) *LIMITATION OF JUDICIAL REVIEW.—There*
 14 *shall be no administrative or judicial review under*
 15 *section 1869, section 1878, or otherwise, of designa-*
 16 *tions made under subparagraph (A) or (B) of para-*
 17 *graph (1).*

18 “(7) *SECRETARY REPORTS.—Not later than*
 19 *April 1 of each year (beginning in 2010), the Sec-*
 20 *retary shall submit a report to Congress and the*
 21 *Comptroller General of the United States that*
 22 *includes—*

23 “(A) *a detailed description of—*

24 “(i) *the total amount expended as a re-*
 25 *sult of the application of this subsection in*

1 *the previous year compared to the total*
2 *amount that would have been expended*
3 *under this title in the year if this subsection*
4 *had not been enacted;*

5 “(ii) *the projections of the total*
6 *amount that will be expended as a result of*
7 *the application of this subsection in the*
8 *year in which the report is submitted com-*
9 *pared to the total amount that would have*
10 *been expended under this title in the year if*
11 *this subsection had not been enacted;*

12 “(iii) *amounts remaining within the*
13 *funding limitation specified in paragraph*
14 *(5); and*

15 “(iv) *the steps that the Secretary will*
16 *take under clauses (i) and (ii) of paragraph*
17 *(5)(B) to ensure that the application of this*
18 *subsection will not cause expenditures to ex-*
19 *ceed the applicable amount described in*
20 *paragraph (5)(A); and*

21 “(B) *a certification from the Chief Actuary*
22 *of the Centers for Medicare & Medicaid Services*
23 *that the descriptions under clauses (i), (ii), (iii),*
24 *and (iv) of subparagraph (A) are reasonable, ac-*

1 *curate, and based on generally accepted actu-*
 2 *arial principles and methodologies.*

3 “(8) *BIENNIAL GAO REPORTS.*—*Not later than*
 4 *January 1, 2011, and biennially thereafter, the*
 5 *Comptroller General of the United States shall submit*
 6 *to the Secretary and Congress a report on the des-*
 7 *ignation of highly competitive regions under this sub-*
 8 *section and the application of the payment system*
 9 *under this subsection within such regions. Each re-*
 10 *port shall include—*

11 “(A) *an evaluation of—*

12 “(i) *the quality of care provided to*
 13 *beneficiaries enrolled in a*
 14 *MedicareAdvantage preferred provider plan*
 15 *in a highly competitive region;*

16 “(ii) *the satisfaction of beneficiaries*
 17 *with benefits under such a plan;*

18 “(iii) *the costs to the medicare pro-*
 19 *gram for payments made to such plans; and*

20 “(iv) *any improvements in the delivery*
 21 *of health care services under such a plan;*

22 “(B) *a comparative analysis of the bench-*
 23 *mark system applicable under the other provi-*
 24 *sions of this section and the payment system ap-*

1 *plicable in highly competitive regions under this*
 2 *subsection; and*

3 *“(C) recommendations for such legislation*
 4 *or administrative action as the Comptroller Gen-*
 5 *eral determines to be appropriate.*

6 *“(9) REPORT ON BUDGET NEUTRALITY FOR FIS-*
 7 *CAL YEARS AFTER 2013.—*

8 *“(A) IN GENERAL.—If the Secretary intends*
 9 *to designate 1 or more regions as highly competi-*
 10 *tive regions with respect to calendar 2014 or any*
 11 *subsequent calendar year, the Secretary shall*
 12 *submit a report to Congress indicating such in-*
 13 *tent no later than April 1 of the calendar year*
 14 *prior to the calendar year in which the applica-*
 15 *ble designation year begins.*

16 *“(B) REQUIREMENTS.—A report submitted*
 17 *under subparagraph (A) shall—*

18 *“(i) specify the steps (if any) that the*
 19 *Secretary will take pursuant to paragraph*
 20 *(5)(B) to ensure that the total amount ex-*
 21 *pended as a result of the application of this*
 22 *subsection during the year will not exceed*
 23 *the applicable amount for the year (as de-*
 24 *finied in paragraph (5)(A)(ii)(II)); and*

1 “(ii) contain a certification from the
 2 Chief Actuary of the Centers for Medicare
 3 and Medicaid Services that such steps will
 4 meet the requirements of paragraph (5)(A)
 5 based on an analysis using generally ac-
 6 cepted actuarial principles and methodolo-
 7 gies.”.

8 (b) CONFORMING AMENDMENT.—Section
 9 1858(c)(3)(A)(i) (as added by section 211(b)) is amended
 10 to read as follows:

11 “(i) Whether each preferred provider
 12 region has been designated as a highly com-
 13 petitive region under subparagraph (A) or
 14 (B) of subsection (i)(1) and the benchmark
 15 amount for any preferred provider region
 16 (as calculated under paragraph (2)(A)) for
 17 the year that has not been designated as a
 18 highly competitive region.”.

19 **SEC. 232. FEE-FOR-SERVICE MODERNIZATION PROJECTS.**

20 (a) ESTABLISHMENT.—

21 (1) REVIEW AND REPORT ON RESULTS OF EXIST-
 22 ING DEMONSTRATIONS.—

23 (A) REVIEW.—The Secretary shall conduct
 24 an empirical review of the results of the dem-
 25 onstrations under sections 442, 443, and 444.

1 (B) *REPORT*.—Not later than January 1,
2 2008, the Secretary shall submit a report to Con-
3 gress on the empirical review conducted under
4 subparagraph (A) which shall include estimates
5 of the total costs of the demonstrations, including
6 expenditures as a result of the provision of serv-
7 ices provided to beneficiaries under the dem-
8 onstrations that are incidental to the services
9 provided under the demonstrations, and all other
10 expenditures under title XVIII of the Social Se-
11 curity Act. The report shall also include a cer-
12 tification from the Chief Actuary of the Centers
13 for Medicare & Medicaid Services that such esti-
14 mates are reasonable, accurate, and based on
15 generally accepted actuarial principles and
16 methodologies.

17 (2) *PROJECTS*.—Beginning in 2009, the Sec-
18 retary, based on the empirical review conducted under
19 paragraph (1), shall establish projects under which
20 medicare beneficiaries receiving benefits under the
21 medicare fee-for-service program under parts A and B
22 of title XVIII of the Social Security Act are provided
23 with coverage of enhanced benefits or services under
24 such program. The purpose of such projects is to

1 *evaluate whether the provision of such enhanced bene-*
 2 *fits or services to such beneficiaries—*

3 *(A) improves the quality of care provided to*
 4 *such beneficiaries under the medicare program;*

5 *(B) improves the health care delivery system*
 6 *under the medicare program; and*

7 *(C) results in reduced expenditures under*
 8 *the medicare program.*

9 *(2) ENHANCED BENEFITS OR SERVICES.—For*
 10 *purposes of this section, enhanced benefits or services*
 11 *shall include—*

12 *(A) preventive services not otherwise covered*
 13 *under title XVIII of the Social Security Act;*

14 *(B) chronic care coordination services;*

15 *(C) disease management services; or*

16 *(D) other benefits or services that the Sec-*
 17 *retary determines will improve preventive health*
 18 *care for medicare beneficiaries, result in im-*
 19 *proved chronic disease management, and man-*
 20 *agement of complex, life-threatening, or high-cost*
 21 *conditions and are consistent with the goals de-*
 22 *scribed in subparagraphs (A), (B), and (C) of*
 23 *paragraph (1).*

24 *(b) PROJECT SITES AND DURATION.—*

1 (1) *IN GENERAL.*—Subject to subsection (e)(2),
 2 the projects under this section shall be conducted—

3 (A) in a region or regions that are com-
 4 parable (as determined by the Secretary) to the
 5 region or regions that are designated as a highly
 6 competitive region under subparagraph (A) or
 7 (B) of section 1858(i)(1) of the Social Security
 8 Act, as added by section 231 of this Act; and

9 (B) during the years that a region or re-
 10 gions are designated as such a highly competitive
 11 region.

12 (2) *RULE OF CONSTRUCTION.*—For purposes of
 13 paragraph (1), a comparable region does not nec-
 14 essarily mean the identical region.

15 (c) *WAIVER AUTHORITY.*—The Secretary shall waive
 16 compliance with the requirements of title XVIII of the So-
 17 cial Security Act (42 U.S.C. 1395 et seq.) only to the extent
 18 and for such period as the Secretary determines is necessary
 19 to provide for enhanced benefits or services consistent with
 20 the projects under this section.

21 (d) *BIENNIAL GAO REPORTS.*—Not later than Janu-
 22 ary 1, 2011, and biennially thereafter for as long as the
 23 projects under this section are being conducted, the Comp-
 24 troller General of the United States shall submit to the Sec-

1 *retary and Congress a report that evaluates the projects.*

2 *Each report shall include—*

3 *(1) an evaluation of—*

4 *(A) the quality of care provided to bene-*
 5 *ficiaries receiving benefits or services under the*
 6 *projects;*

7 *(B) the satisfaction of beneficiaries receiv-*
 8 *ing benefits or services under the projects;*

9 *(C) the costs to the medicare program under*
 10 *the projects; and*

11 *(D) any improvements in the delivery of*
 12 *health care services under the projects; and*

13 *(2) recommendations for such legislation or ad-*
 14 *ministrative action as the Comptroller General deter-*
 15 *mines to be appropriate.*

16 *(e) FUNDING.—*

17 *(1) IN GENERAL.—Payments for the costs of car-*
 18 *rying out the projects under this section shall be made*
 19 *from the Federal Hospital Insurance Trust Fund*
 20 *under section 1817 of the Social Security Act (42*
 21 *U.S.C. 1395i) and the Federal Supplementary Insur-*
 22 *ance Trust Fund under section 1841 of such Act (42*
 23 *U.S.C. 1395t), as determined appropriate by the Sec-*
 24 *retary.*

1 (2) *LIMITATION.*—*The total amount expended*
 2 *under the medicare fee-for-service program under*
 3 *parts A and B of title XVIII of the Social Security*
 4 *Act (including all amounts expended as a result of the*
 5 *projects under this section) during the period or year,*
 6 *as applicable, may not exceed—*

7 (A) *for the period beginning on January 1,*
 8 *2009, and ending on September 30, 2013, an*
 9 *amount equal to the total amount that would*
 10 *have been expended under the medicare fee-for-*
 11 *service program under parts A and B of title*
 12 *XVIII of the Social Security Act during the pe-*
 13 *riod if the projects had not been conducted plus*
 14 *\$6,000,000,000; and*

15 (B) *for fiscal year 2014 and any subsequent*
 16 *fiscal year, an amount equal to the total amount*
 17 *that would have been expended under the medi-*
 18 *care fee-for-service program under parts A and B*
 19 *of such title during the year if the projects had*
 20 *not been conducted.*

21 (3) *MONITORING AND REPORTS.*—

22 (A) *ONGOING MONITORING BY THE SEC-*
 23 *RETARY TO ENSURE FUNDING LIMITATION IS NOT*
 24 *VIOLATED.*—*The Secretary shall continually*
 25 *monitor expenditures made under title XVIII of*

1 *the Social Security Act by reason of the projects*
2 *under this section to ensure that the limitations*
3 *described in subparagraphs (A) and (B) of para-*
4 *graph (2) are not violated.*

5 *(B) REPORTS.—Not later than April 1 of*
6 *each year (beginning in 2010), the Secretary*
7 *shall submit a report to Congress and the Comp-*
8 *troller General of the United States that*
9 *includes—*

10 *(i) a detailed description of—*

11 *(I) the total amount expended*
12 *under the medicare fee-for-service pro-*
13 *gram under parts A and B of title*
14 *XVIII of the Social Security Act (in-*
15 *cluding all amounts expended as a re-*
16 *sult of the projects under this section)*
17 *during the previous year compared to*
18 *the total amount that would have been*
19 *expended under the original medicare*
20 *fee-for-service program in the year if*
21 *the projects had not been conducted;*

22 *(II) the projections of the total*
23 *amount expended under the medicare*
24 *fee-for-service program under parts A*
25 *and B of title XVIII of the Social Se-*

1 *curity Act (including all amounts ex-*
2 *pended as a result of the projects under*
3 *this section) during the year in which*
4 *the report is submitted compared to the*
5 *total amount that would have been ex-*
6 *pended under the original medicare*
7 *fee-for-service program in the year if*
8 *the projects had not been conducted;*

9 *(III) amounts remaining within*
10 *the funding limitation specified in*
11 *paragraph (2); and*

12 *(IV) how the Secretary will*
13 *change the scope, site, and duration of*
14 *the projects in subsequent years in*
15 *order to ensure that the limitations de-*
16 *scribed in subparagraphs (A) and (B)*
17 *of paragraph (2) are not violated; and*

18 *(ii) a certification from the Chief Actu-*
19 *ary of the Centers for Medicare & Medicaid*
20 *Services that the descriptions under sub-*
21 *clauses (I), (II), (III), and (IV) of clause (i)*
22 *are reasonable, accurate, and based on gen-*
23 *erally accepted actuarial principles and*
24 *methodologies.*

1 (C) *REPORT ON BUDGET NEUTRALITY FOR*
2 *FISCAL YEARS AFTER 2013.*—

3 (i) *IN GENERAL.*—*If the Secretary in-*
4 *tends to continue the projects under this sec-*
5 *tion for fiscal year 2014 or any subsequent*
6 *fiscal year, the Secretary shall submit a re-*
7 *port to Congress indicating such intent no*
8 *later than April 1 of the year prior to the*
9 *year in which the fiscal year begins.*

10 (ii) *REQUIREMENTS.*—*A report sub-*
11 *mitted under clause (i) shall—*

12 (I) *specify the steps (if any) that*
13 *the Secretary will take pursuant to*
14 *paragraph (4) to ensure that the limi-*
15 *tations described in paragraph (2)(B)*
16 *will not be violated for the year; and*

17 (II) *contain a certification from*
18 *the Chief Actuary of the Centers for*
19 *Medicare and Medicaid Services that*
20 *such steps will meet the requirements*
21 *of paragraph (2) based on an analysis*
22 *using generally accepted actuarial*
23 *principles and methodologies.*

24 (4) *APPLICATION OF LIMITATION.*—*If the Sec-*
25 *retary determines that the projects under this section*

1 *will cause the limitations described in subparagraphs*
 2 *(A) and (B) of paragraph (2) to be violated, the Sec-*
 3 *retary shall take appropriate steps to reduce spending*
 4 *under the projects, including through reducing the*
 5 *scope, site, and duration of the projects.*

6 (5) *AUTHORITY.—Beginning in 2014, the Sec-*
 7 *retary shall make necessary spending adjustments*
 8 *(including pro rata reductions in payments to health*
 9 *care providers under the medicare program) to recoup*
 10 *amounts so that the limitations described in subpara-*
 11 *graphs (A) and (B) of paragraph (2) are not violated.*

12 ***Subtitle E—National Bipartisan***
 13 ***Commission on Medicare Reform***

14 ***SEC. 241. MEDICAREADVANTAGE GOAL; ESTABLISHMENT OF***
 15 ***COMMISSION.***

16 (a) *ENROLLMENT GOAL.—It is the goal of this title*
 17 *that, not later than January 1, 2010, at least 15 percent*
 18 *of individuals entitled to, or enrolled for, benefits under*
 19 *part A of title XVIII of the Social Security Act and enrolled*
 20 *under part B of such title should be enrolled in a*
 21 *MedicareAdvantage plan, as determined by the Center for*
 22 *Medicare Choices.*

23 (b) *FAILURE TO ACHIEVE GOAL.—If the goal described*
 24 *in subsection (a) is not met by January 1, 2012, as deter-*

1 mined by the Center for Medicare Choices, there shall be
 2 established a commission as described in section 2.

3 **SEC. 242. NATIONAL BIPARTISAN COMMISSION ON MEDI-**
 4 **CARE REFORM.**

5 (a) *ESTABLISHMENT.*—Upon a determination under
 6 section 241(b) that the enrollment goal has not been met,
 7 there shall be established a commission to be known as the
 8 National Bipartisan Commission on Medicare Reform (in
 9 this section referred to as the “Commission”).

10 (b) *DUTIES OF THE COMMISSION.*—The Commission
 11 shall—

12 (1) review and analyze the long-term financial
 13 condition of the medicare program under title XVIII
 14 of the Social Security Act (42 U.S.C. 1395 et seq.);

15 (2) identify problems that threaten the financial
 16 integrity of the Federal Hospital Insurance Trust
 17 Fund and the Federal Supplementary Medical Insur-
 18 ance Trust Fund established under sections 1817 and
 19 1841 of such Act (42 U.S.C. 1395i and 1395t),
 20 including—

21 (A) the financial impact on the medicare
 22 program of the significant increase in the num-
 23 ber of medicare eligible individuals; and

24 (B) the ability of the Federal Government to
 25 sustain the program into the future;

1 (3) analyze potential solutions to the problems
2 identified under paragraph (2) that will ensure both
3 the financial integrity of the medicare program and
4 the provision of appropriate benefits under such pro-
5 gram, including methods used by other nations to re-
6 spond to comparable demographic patterns in eligi-
7 bility for health care benefits for elderly and disabled
8 individuals and trends in employment-related health
9 care for retirees;

10 (4) make recommendations to restore the solvency
11 of the Federal Hospital Insurance Trust Fund and
12 the financial integrity of the Federal Supplementary
13 Medical Insurance Trust Fund;

14 (5) make recommendations for establishing the
15 appropriate financial structure of the medicare pro-
16 gram as a whole;

17 (6) make recommendations for establishing the
18 appropriate balance of benefits covered under, and
19 beneficiary contributions to, the medicare program;

20 (7) make recommendations for the time periods
21 during which the recommendations described in para-
22 graphs (4), (5) and (6) should be implemented;

23 (8) make recommendations on the impact of
24 chronic disease and disability trends on future costs
25 and quality of services under the current benefit, fi-

1 *nancing, and delivery system structure of the medi-*
 2 *care program;*

3 *(9) make recommendations regarding a com-*
 4 *prehensive approach to preserve the medicare pro-*
 5 *gram, including ways to increase the effectiveness of*
 6 *the MedicareAdvantage program and to increase*
 7 *MedicareAdvantage enrollment rates; and*

8 *(10) review and analyze such other matters as*
 9 *the Commission determines appropriate.*

10 *(c) MEMBERSHIP.—*

11 *(1) NUMBER AND APPOINTMENT.—The Commis-*
 12 *sion shall be composed of 17 members, of whom—*

13 *(A) four shall be appointed by the Presi-*
 14 *dent;*

15 *(B) six shall be appointed by the Majority*
 16 *Leader of the Senate, in consultation with the*
 17 *Minority Leader of the Senate, of whom not*
 18 *more than 4 shall be of the same political party;*

19 *(C) six shall be appointed by the Speaker of*
 20 *the House of Representatives, in consultation*
 21 *with the Minority Leader of the House of Rep-*
 22 *resentatives, of whom not more than 4 shall be*
 23 *of the same political party; and*

24 *(D) one, who shall serve as Chairperson of*
 25 *the Commission, shall be appointed jointly by*

1 *the President, Majority Leader of the Senate,*
2 *and the Speaker of the House of Representatives.*

3 (2) *DEADLINE FOR APPOINTMENT.*—*Members of*
4 *the Commission shall be appointed by not later than*
5 *October 1, 2012.*

6 (3) *TERMS OF APPOINTMENT.*—*The term of any*
7 *member appointed under paragraph (1) shall be for*
8 *the life of the Commission.*

9 (4) *MEETINGS.*—*The Commission shall meet at*
10 *the call of the Chairperson or a majority of its mem-*
11 *bers.*

12 (5) *QUORUM.*—*A quorum for purposes of con-*
13 *ducting the business of the Commission shall consist*
14 *of 8 members of the Commission, except that 4 mem-*
15 *bers may conduct a hearing under subsection (e).*

16 (6) *VACANCIES.*—*A vacancy in the membership*
17 *of the Commission shall be filled, not later than 30*
18 *days after the Commission is given notice of the va-*
19 *cancy, in the same manner in which the original ap-*
20 *pointment was made. Such a vacancy shall not affect*
21 *the power of the remaining members to carry out the*
22 *duties of the Commission.*

23 (7) *COMPENSATION.*—*Members of the Commis-*
24 *sion shall receive no additional pay, allowances, or*
25 *benefits by reason of their service on the Commission.*

1 (8) *EXPENSES.*—*Each member of the Commis-*
 2 *sion shall receive travel expenses and per diem in lieu*
 3 *of subsistence in accordance with sections 5702 and*
 4 *5703 of title 5, United States Code.*

5 (d) *STAFF AND SUPPORT SERVICES.*—

6 (1) *EXECUTIVE DIRECTOR.*—

7 (A) *APPOINTMENT.*—*The Chairperson shall*
 8 *appoint an executive director of the Commission.*

9 (B) *COMPENSATION.*—*The executive director*
 10 *shall be paid the rate of basic pay for level V of*
 11 *the Executive Schedule under title 5, United*
 12 *States Code.*

13 (2) *STAFF.*—*With the approval of the Commis-*
 14 *sion, the executive director may appoint such per-*
 15 *sonnel as the executive director considers appropriate.*

16 (3) *APPLICABILITY OF CIVIL SERVICE LAWS.*—
 17 *The staff of the Commission shall be appointed with-*
 18 *out regard to the provisions of title 5, United States*
 19 *Code, governing appointments in the competitive serv-*
 20 *ice, and shall be paid without regard to the provisions*
 21 *of chapter 51 and subchapter III of chapter 53 of such*
 22 *title (relating to classification and General Schedule*
 23 *pay rates).*

24 (4) *EXPERTS AND CONSULTANTS.*—*With the ap-*
 25 *proval of the Commission, the executive director may*

1 *procure temporary and intermittent services under*
 2 *section 3109(b) of title 5, United States Code.*

3 (5) *PHYSICAL FACILITIES.*—*The Administrator*
 4 *of the General Services Administration shall locate*
 5 *suitable office space for the operation of the Commis-*
 6 *sion. The facilities shall serve as the headquarters of*
 7 *the Commission and shall include all necessary equip-*
 8 *ment and incidentals required for the proper func-*
 9 *tioning of the Commission.*

10 (i) *POWERS OF COMMISSION.*—

11 (1) *HEARINGS AND OTHER ACTIVITIES.*—*The*
 12 *Commission may hold such hearings and undertake*
 13 *such other activities as the Commission determines to*
 14 *be necessary to carry out its duties under this section.*

15 (2) *STUDIES BY GAO.*—*Upon the request of the*
 16 *Commission, the Comptroller General shall conduct*
 17 *such studies or investigations as the Commission de-*
 18 *termines to be necessary to carry out its duties under*
 19 *this section.*

20 (3) *COST ESTIMATES BY CONGRESSIONAL BUDG-*
 21 *ET OFFICE AND OFFICE OF THE CHIEF ACTUARY OF*
 22 *THE CENTERS FOR MEDICARE & MEDICAID.*—

23 (A) *IN GENERAL.*—*The Director of the Con-*
 24 *gressional Budget Office or the Chief Actuary of*
 25 *the Center for Medicare & Medicaid Services, or*

1 *both, shall provide to the Commission, upon the*
2 *request of the Commission, such cost estimates as*
3 *the Commission determines to be necessary to*
4 *carry out its duties under this section.*

5 *(B) REIMBURSEMENTS.—The Commission*
6 *shall reimburse the Director of the Congressional*
7 *Budget Office for expenses relating to the em-*
8 *ployment in the office of the Director of such ad-*
9 *ditional staff as may be necessary for the Direc-*
10 *tor to comply with requests by the Commission*
11 *under subparagraph (A).*

12 *(4) DETAIL OF FEDERAL EMPLOYEES.—Upon the*
13 *request of the Commission, the head of any Federal*
14 *agency is authorized to detail, without reimburse-*
15 *ment, any of the personnel of such agency to the Com-*
16 *mission to assist the Commission in carrying out its*
17 *duties under this section. Any such detail shall not*
18 *interrupt or otherwise affect the civil service status or*
19 *privileges of the Federal employee.*

20 *(5) TECHNICAL ASSISTANCE.—Upon the request*
21 *of the Commission, the head of a Federal agency shall*
22 *provide such technical assistance to the Commission*
23 *as the Commission determines to be necessary to*
24 *carry out its duties under this section.*

1 (6) *USE OF MAILS.*—*The Commission may use*
2 *the United States mails in the same manner and*
3 *under the same conditions as Federal agencies and*
4 *shall, for purposes of the frank, be considered a com-*
5 *mission of Congress as described in section 3215 of*
6 *title 39, United States Code.*

7 (7) *OBTAINING INFORMATION.*—*The Commission*
8 *may secure directly from any Federal agency infor-*
9 *mation necessary to enable it to carry out its duties*
10 *under this section, if the information may be disclosed*
11 *under section 552 of title 5, United States Code.*
12 *Upon request of the Chairperson of the Commission,*
13 *the head of each such agency shall furnish such infor-*
14 *mation to the Commission.*

15 (8) *ADMINISTRATIVE SUPPORT SERVICES.*—*Upon*
16 *the request of the Commission, the Administrator of*
17 *General Services shall provide to the Commission on*
18 *a reimbursable basis such administrative support*
19 *services as the Commission may request.*

20 (9) *PRINTING.*—*For purposes of costs relating to*
21 *printing and binding, including the cost of personnel*
22 *detailed from the Government Printing Office, the*
23 *Commission shall be deemed to be a committee of*
24 *Congress.*

1 (f) *REPORT*.—Not later than April 1, 2014, the Com-
 2 mission shall submit to the President and Congress a report
 3 and an implementation bill that shall contain a detailed
 4 statement of only those recommendations, findings, and
 5 conclusions of the Commission that receive the approval of
 6 at least 11 members of the Commission.

7 (g) *TERMINATION*.—The Commission shall terminate
 8 on the date that is 30 days after the date on which the re-
 9 port and implementation bill is submitted under subsection
 10 (f).

11 **SEC. 243. CONGRESSIONAL CONSIDERATION OF REFORM**
 12 **PROPOSALS.**

13 (a) *DEFINITIONS*.—In this section:

14 (1) *IMPLEMENTATION BILL*.—The term “imple-
 15 mentation bill” means only a bill that is introduced
 16 as provided under subsection (b), and contains the
 17 proposed legislation included in the report submitted
 18 to Congress under section 242(f), without modifica-
 19 tion.

20 (2) *CALENDAR DAY*.—The term “calendar day”
 21 means a calendar day other than 1 on which either
 22 House is not in session because of an adjournment of
 23 more than 3 days to a date certain.

24 (b) *INTRODUCTION; REFERRAL; AND REPORT OR DIS-*
 25 *CHARGE*.—

1 (1) *INTRODUCTION.*—*On the first calendar day*
2 *on which both Houses are in session immediately fol-*
3 *lowing the date on which the report is submitted to*
4 *Congress under section 242(f), a single implementa-*
5 *tion bill shall be introduced (by request)—*

6 *(A) in the Senate by the Majority Leader of*
7 *the Senate, for himself and the Minority Leader*
8 *of the Senate, or by Members of the Senate des-*
9 *ignated by the Majority Leader and Minority*
10 *Leader of the Senate; and*

11 *(B) in the House of Representatives by the*
12 *Speaker of the House of Representatives, for him-*
13 *self and the Minority Leader of the House of*
14 *Representatives, or by Members of the House of*
15 *Representatives designated by the Speaker and*
16 *Minority Leader of the House of Representatives.*

17 (2) *REFERRAL.*—*The implementation bills intro-*
18 *duced under paragraph (1) shall be referred to any*
19 *appropriate committee of jurisdiction in the Senate*
20 *and any appropriate committee of jurisdiction in the*
21 *House of Representatives. A committee to which an*
22 *implementation bill is referred under this paragraph*
23 *may report such bill to the respective House without*
24 *amendment.*

1 (3) *REPORT OR DISCHARGE.*—If a committee to
 2 which an implementation bill is referred has not re-
 3 ported such bill by the end of the 15th calendar day
 4 after the date of the introduction of such bill, such
 5 committee shall be immediately discharged from fur-
 6 ther consideration of such bill, and upon being re-
 7 ported or discharged from the committee, such bill
 8 shall be placed on the appropriate calendar.

9 (c) *FLOOR CONSIDERATION.*—

10 (1) *IN GENERAL.*—When the committee to which
 11 an implementation bill is referred has reported, or
 12 has been discharged under subsection (b)(3), it is at
 13 any time thereafter in order (even though a previous
 14 motion to the same effect has been disagreed to) for
 15 any Member of the respective House to move to pro-
 16 ceed to the consideration of the implementation bill,
 17 and all points of order against the implementation
 18 bill (and against consideration of the implementation
 19 bill) are waived. The motion is highly privileged in
 20 the House of Representatives and is privileged in the
 21 Senate. The motion is not subject to amendment, or
 22 to a motion to postpone, or to a motion to proceed to
 23 the consideration of other business. A motion to recon-
 24 sider the vote by which the motion is agreed to or dis-
 25 agreed to shall not be in order. If a motion to proceed

1 *to the consideration of the implementation bill is*
 2 *agreed to, the implementation bill shall remain the*
 3 *unfinished business of the respective House until dis-*
 4 *posed of.*

5 (2) *AMENDMENTS.—An implementation bill may*
 6 *not be amended in the Senate or the House of Rep-*
 7 *resentatives.*

8 (3) *DEBATE.—Debate on the implementation*
 9 *bill, and on all debatable motions and appeals in con-*
 10 *nection therewith, shall be limited to not more than*
 11 *20 hours, which shall be divided equally between those*
 12 *favoring and those opposing the resolution. A motion*
 13 *further to limit debate is in order and not debatable.*
 14 *An amendment to, or a motion to postpone, or a mo-*
 15 *tion to proceed to the consideration of other business,*
 16 *or a motion to recommit the implementation bill is*
 17 *not in order. A motion to reconsider the vote by which*
 18 *the implementation bill is agreed to or disagreed to*
 19 *is not in order.*

20 (4) *VOTE ON FINAL PASSAGE.—Immediately fol-*
 21 *lowing the conclusion of the debate on an implemen-*
 22 *tation bill, and a single quorum call at the conclusion*
 23 *of the debate if requested in accordance with the rules*
 24 *of the appropriate House, the vote on final passage of*
 25 *the implementation bill shall occur.*

1 (5) *RULINGS OF THE CHAIR ON PROCEDURE.*—
 2 *Appeals from the decisions of the Chair relating to the*
 3 *application of the rules of the Senate or the House of*
 4 *Representatives, as the case may be, to the procedure*
 5 *relating to an implementation bill shall be decided*
 6 *without debate.*

7 (d) *COORDINATION WITH ACTION BY OTHER*
 8 *HOUSE.*—*If, before the passage by 1 House of an implemen-*
 9 *tation bill of that House, that House receives from the other*
 10 *House an implementation bill, then the following proce-*
 11 *dures shall apply:*

12 (1) *NONREFERRAL.*—*The implementation bill of*
 13 *the other House shall not be referred to a committee.*

14 (2) *VOTE ON BILL OF OTHER HOUSE.*—*With re-*
 15 *spect to an implementation bill of the House receiving*
 16 *the implementation bill—*

17 (A) *the procedure in that House shall be the*
 18 *same as if no implementation bill had been re-*
 19 *ceived from the other House; but*

20 (B) *the vote on final passage shall be on the*
 21 *implementation bill of the other House.*

22 (e) *RULES OF SENATE AND HOUSE OF REPRESENTA-*
 23 *TIVES.*—*This section is enacted by Congress—*

24 (1) *as an exercise of the rulemaking power of the*
 25 *Senate and House of Representatives, respectively,*

1 *and as such it is deemed a part of the rules of each*
 2 *House, respectively, but applicable only with respect*
 3 *to the procedure to be followed in that House in the*
 4 *case of an implementation bill described in subsection*
 5 *(a), and it supersedes other rules only to the extent*
 6 *that it is inconsistent with such rules; and*

7 *(2) with full recognition of the constitutional*
 8 *right of either House to change the rules (so far as re-*
 9 *lating to the procedure of that House) at any time,*
 10 *in the same manner, and to the same extent as in the*
 11 *case of any other rule of that House.*

12 **SEC. 244. AUTHORIZATION OF APPROPRIATIONS.**

13 *There are authorized to be appropriated such sums as*
 14 *may be necessary to carry out this subtitle for each of fiscal*
 15 *years 2012 through 2013.*

16 **TITLE III—CENTER FOR**
 17 **MEDICARE CHOICES**

18 **SEC. 301. ESTABLISHMENT OF THE CENTER FOR MEDICARE**
 19 **CHOICES.**

20 *(a) IN GENERAL.—Title XVIII (42 U.S.C. 1395 et*
 21 *seq.), as amended by section 111, is amended by inserting*
 22 *after 1806 the following new section:*

23 *“ESTABLISHMENT OF THE CENTER FOR MEDICARE*
 24 *CHOICES*

25 *“SEC. 1808. (a) ESTABLISHMENT.—By not later than*
 26 *March 1, 2004, the Secretary shall establish within the De-*

1 *partment of Health and Human Services the Center for*
 2 *Medicare Choices, which shall be separate from the Centers*
 3 *for Medicare & Medicaid Services.*

4 “(b) ADMINISTRATOR AND DEPUTY ADMINIS-
 5 TRATOR.—

6 “(1) ADMINISTRATOR.—

7 “(A) IN GENERAL.—*The Center for Medi-*
 8 *care Choices shall be headed by an Adminis-*
 9 *trator (in this section referred to as the ‘Admin-*
 10 *istrator’) who shall be appointed by the Presi-*
 11 *dent, by and with the advice and consent of the*
 12 *Senate. The Administrator shall report directly*
 13 *to the Secretary.*

14 “(B) COMPENSATION.—*The Administrator*
 15 *shall be paid at the rate of basic pay payable for*
 16 *level III of the Executive Schedule under section*
 17 *5314 of title 5, United States Code.*

18 “(C) TERM OF OFFICE.—*The Administrator*
 19 *shall be appointed for a term of 5 years. In any*
 20 *case in which a successor does not take office at*
 21 *the end of an Administrator’s term of office, that*
 22 *Administrator may continue in office until the*
 23 *entry upon office of such a successor. An Admin-*
 24 *istrator appointed to a term of office after the*
 25 *commencement of such term may serve under*

1 *such appointment only for the remainder of such*
2 *term.*

3 “(D) *GENERAL AUTHORITY.*—*The Adminis-*
4 *trator shall be responsible for the exercise of all*
5 *powers and the discharge of all duties of the Cen-*
6 *ter for Medicare Choices, and shall have author-*
7 *ity and control over all personnel and activities*
8 *thereof.*

9 “(E) *RULEMAKING AUTHORITY.*—*The Ad-*
10 *ministrator may prescribe such rules and regula-*
11 *tions as the Administrator determines necessary*
12 *or appropriate to carry out the functions of the*
13 *Center for Medicare Choices. The regulations pre-*
14 *scribed by the Administrator shall be subject to*
15 *the rulemaking procedures established under sec-*
16 *tion 553 of title 5, United States Code.*

17 “(F) *AUTHORITY TO ESTABLISH ORGANIZA-*
18 *TIONAL UNITS.*—*The Administrator may estab-*
19 *lish, alter, consolidate, or discontinue such orga-*
20 *nizational units or components within the Cen-*
21 *ter for Medicare Choices as the Administrator*
22 *considers necessary or appropriate, except that*
23 *this subparagraph shall not apply with respect*
24 *to any unit, component, or provision provided*
25 *for by this section.*

1 “(G) *AUTHORITY TO DELEGATE.*—*The Ad-*
 2 *ministrator may assign duties, and delegate, or*
 3 *authorize successive redelegations of, authority to*
 4 *act and to render decisions, to such officers and*
 5 *employees of the Center for Medicare Choices as*
 6 *the Administrator may find necessary. Within*
 7 *the limitations of such delegations, redelegations,*
 8 *or assignments, all official acts and decisions of*
 9 *such officers and employees shall have the same*
 10 *force and effect as though performed or rendered*
 11 *by the Administrator.*

12 “(2) *DEPUTY ADMINISTRATOR.*—

13 “(A) *IN GENERAL.*—*There shall be a Dep-*
 14 *uty Administrator of the Center for Medicare*
 15 *Choices who shall be appointed by the Adminis-*
 16 *trator.*

17 “(B) *COMPENSATION.*—*The Deputy Admin-*
 18 *istrator shall be paid at the rate of basic pay*
 19 *payable for level IV of the Executive Schedule*
 20 *under section 5315 of title 5, United States Code.*

21 “(C) *TERM OF OFFICE.*—*The Deputy Ad-*
 22 *ministrator shall be appointed for a term of 5*
 23 *years. In any case in which a successor does not*
 24 *take office at the end of a Deputy Administra-*
 25 *tor’s term of office, such Deputy Administrator*

1 *may continue in office until the entry upon of-*
 2 *fice of such a successor. A Deputy Administrator*
 3 *appointed to a term of office after the commence-*
 4 *ment of such term may serve under such ap-*
 5 *pointment only for the remainder of such term.*

6 “(D) *DUTIES.—The Deputy Administrator*
 7 *shall perform such duties and exercise such pow-*
 8 *ers as the Administrator shall from time to time*
 9 *assign or delegate. The Deputy Administrator*
 10 *shall be the Acting Administrator of the Center*
 11 *for Medicare Choices during the absence or dis-*
 12 *ability of the Administrator and, unless the*
 13 *President designates another officer of the Gov-*
 14 *ernment as Acting Administrator, in the event of*
 15 *a vacancy in the office of the Administrator.*

16 “(3) *SECRETARIAL COORDINATION OF PROGRAM*
 17 *ADMINISTRATION.—The Secretary shall ensure appro-*
 18 *priate coordination between the Administrator and*
 19 *the Administrator of the Centers for Medicare & Med-*
 20 *icaid Services in carrying out the programs under*
 21 *this title.*

22 “(c) *DUTIES; ADMINISTRATIVE PROVISIONS.—*

23 “(1) *DUTIES.—*

1 “(A) *GENERAL DUTIES.*—*The Adminis-*
 2 *trator shall carry out parts C and D,*
 3 *including—*

4 “(i) *negotiating, entering into, and en-*
 5 *forcing, contracts with plans for the offering*
 6 *of MedicareAdvantage plans under part C,*
 7 *including the offering of qualified prescrip-*
 8 *tion drug coverage under such plans; and*

9 “(ii) *negotiating, entering into, and*
 10 *enforcing, contracts with eligible entities for*
 11 *the offering of Medicare Prescription Drug*
 12 *plans under part D.*

13 “(B) *OTHER DUTIES.*—*The Administrator*
 14 *shall carry out any duty provided for under part*
 15 *C or D, including duties relating to—*

16 “(i) *reasonable cost contracts with eli-*
 17 *gible organizations under section 1876(h);*
 18 *and*

19 “(ii) *demonstration projects carried*
 20 *out in part or in whole under such parts,*
 21 *including the demonstration project carried*
 22 *out through a MedicareAdvantage (formerly*
 23 *Medicare+Choice) project that demonstrates*
 24 *the application of capitation payment rates*
 25 *for frail elderly medicare beneficiaries*

1 *through the use of an interdisciplinary*
 2 *team and through the provision of primary*
 3 *care services to such beneficiaries by means*
 4 *of such a team at the nursing facility in-*
 5 *volved.*

6 “(C) *NONINTERFERENCE.*—*In order to pro-*
 7 *mote competition under parts C and D, the Ad-*
 8 *ministrator, in carrying out the duties required*
 9 *under this section, may not, to the extent pos-*
 10 *sible, interfere in any way with negotiations be-*
 11 *tween eligible entities, MedicareAdvantage orga-*
 12 *nizations, hospitals, physicians, other entities or*
 13 *individuals furnishing items and services under*
 14 *this title (including contractors for such items*
 15 *and services), and drug manufacturers, whole-*
 16 *salers, or other suppliers of covered drugs*

17 “(D) *ANNUAL REPORTS.*—*Not later than*
 18 *March 31 of each year, the Administrator shall*
 19 *submit to Congress and the President a report on*
 20 *the administration of the voluntary prescription*
 21 *drug delivery program under this part during*
 22 *the previous fiscal year.*

23 “(2) *MANAGEMENT STAFF.*—

24 “(A) *IN GENERAL.*—*The Administrator,*
 25 *with the approval of the Secretary, may employ,*

1 *such management staff as determined appro-*
 2 *priate. Any such manager shall be required to*
 3 *have demonstrated, by their education and expe-*
 4 *rience (either in the public or private sector), su-*
 5 *perior expertise in the following areas:*

6 *“(i) The review, negotiation, and ad-*
 7 *ministration of health care contracts.*

8 *“(ii) The design of health care benefit*
 9 *plans.*

10 *“(iii) Actuarial sciences.*

11 *“(iv) Compliance with health plan con-*
 12 *tracts.*

13 *“(v) Consumer education and decision*
 14 *making.*

15 *“(B) COMPENSATION.—*

16 *“(i) IN GENERAL.—Subject to clause*
 17 *(ii), the Administrator shall establish the*
 18 *rate of pay for an individual employed*
 19 *under subparagraph (A).*

20 *“(ii) MAXIMUM RATE.—In no case*
 21 *may the rate of compensation determined*
 22 *under clause (i) exceed the highest rate of*
 23 *basic pay for the Senior Executive Service*
 24 *under section 5382(b) of title 5, United*
 25 *States Code.*

1 “(3) *REDELEGATION OF CERTAIN FUNCTIONS OF*
2 *THE CENTERS FOR MEDICARE & MEDICAID SERV-*
3 *ICES.*—

4 “(A) *IN GENERAL.*—*The Secretary, the Ad-*
5 *ministrator of the Center for Medicare Choices,*
6 *and the Administrator of the Centers for Medi-*
7 *care & Medicaid Services shall establish an ap-*
8 *propriate transition of responsibility in order to*
9 *redelegate the administration of part C from the*
10 *Secretary and the Administrator of the Centers*
11 *for Medicare & Medicaid Services to the Admin-*
12 *istrator of the Center for Medicare Choices as is*
13 *appropriate to carry out the purposes of this sec-*
14 *tion.*

15 “(B) *TRANSFER OF DATA AND INFORMA-*
16 *TION.*—*The Secretary shall ensure that the Ad-*
17 *ministrator of the Centers for Medicare & Med-*
18 *icaid Services transfers to the Administrator*
19 *such information and data in the possession of*
20 *the Administrator of the Centers for Medicare &*
21 *Medicaid Services as the Administrator requires*
22 *to carry out the duties described in paragraph*
23 *(1).*

24 “(C) *CONSTRUCTION.*—*Insofar as a respon-*
25 *sibility of the Secretary or the Administrator of*

1 *the Centers for Medicare & Medicaid Services is*
 2 *redelegated to the Administrator under this sec-*
 3 *tion, any reference to the Secretary or the Ad-*
 4 *ministrator of the Centers for Medicare & Med-*
 5 *icaid Services in this title or title XI with re-*
 6 *spect to such responsibility is deemed to be a ref-*
 7 *erence to the Administrator.*

8 “(d) *OFFICE OF BENEFICIARY ASSISTANCE.*—

9 “(1) *ESTABLISHMENT.*—*The Secretary shall es-*
 10 *tablish within the Center for Medicare Choices an Of-*
 11 *fice of Beneficiary Assistance to carry out functions*
 12 *relating to medicare beneficiaries under this title, in-*
 13 *cluding making determinations of eligibility of indi-*
 14 *viduals for benefits under this title, providing for en-*
 15 *rollment of medicare beneficiaries under this title,*
 16 *and the functions described in paragraph (2). The Of-*
 17 *fice shall be a separate operating division within the*
 18 *Center for Medicare Choices.*

19 “(2) *DISSEMINATION OF INFORMATION ON BENE-*
 20 *FITS AND APPEALS RIGHTS.*—

21 “(A) *DISSEMINATION OF BENEFITS INFOR-*
 22 *MATION.*—*The Office of Beneficiary Assistance*
 23 *shall disseminate to medicare beneficiaries, by*
 24 *mail, by posting on the Internet site of the Cen-*
 25 *ter for Medicare Choices, and through the toll-*

1 *free telephone number provided for under section*
 2 *1804(b), information with respect to the fol-*
 3 *lowing:*

4 “(i) *Benefits, and limitations on pay-*
 5 *ment (including cost-sharing, stop-loss pro-*
 6 *visions, and formulary restrictions) under*
 7 *parts C and D.*

8 “(ii) *Benefits, and limitations on pay-*
 9 *ment under parts A, and B, including in-*
 10 *formation on medicare supplemental poli-*
 11 *cies under section 1882.*

12 “(iii) *Other areas determined to be ap-*
 13 *propriate by the Administrator.*

14 *Such information shall be presented in a manner*
 15 *so that medicare beneficiaries may compare ben-*
 16 *efits under parts A, B, and D, and medicare*
 17 *supplemental policies with benefits under*
 18 *MedicareAdvantage plans under part C.*

19 “(B) *DISSEMINATION OF APPEALS RIGHTS*
 20 *INFORMATION.—The Office of Beneficiary Assist-*
 21 *ance shall disseminate to medicare beneficiaries*
 22 *in the manner provided under subparagraph (A)*
 23 *a description of procedural rights (including*
 24 *grievance and appeals procedures) of bene-*
 25 *ficiaries under the original medicare fee-for-serv-*

ice program under parts A and B, the MedicareAdvantage program under part C, and the voluntary prescription drug delivery program under part D.

“(3) *MEDICARE OMBUDSMAN.*—

“(A) *IN GENERAL.*—Within the Office of Beneficiary Assistance, there shall be a Medicare Ombudsman, appointed by the Secretary from among individuals with expertise and experience in the fields of health care and advocacy, to carry out the duties described in subparagraph (B).

“(B) *DUTIES.*—The Medicare Ombudsman shall—

“(i) receive complaints, grievances, and requests for information submitted by a medicare beneficiary, with respect to any aspect of the medicare program;

“(ii) provide assistance with respect to complaints, grievances, and requests referred to in clause (i), including—

“(I) assistance in collecting relevant information for such beneficiaries, to seek an appeal of a decision or determination made by a fiscal

1 *intermediary, carrier,*
 2 *MedicareAdvantage organization, an*
 3 *eligible entity under part D, or the*
 4 *Secretary; and*

5 *“(II) assistance to such bene-*
 6 *ficiaries with any problems arising*
 7 *from disenrollment from a*
 8 *MedicareAdvantage plan under part C*
 9 *or a prescription drug plan under part*
 10 *D; and*

11 *“(iii) submit annual reports to Con-*
 12 *gress, the Secretary, and the Medicare Com-*
 13 *petitive Policy Advisory Board describing*
 14 *the activities of the Office, and including*
 15 *such recommendations for improvement in*
 16 *the administration of this title as the Om-*
 17 *budsman determines appropriate.*

18 *“(C) COORDINATION WITH STATE OMBUDS-*
 19 *MAN PROGRAMS AND CONSUMER ORGANIZA-*
 20 *TIONS.—The Medicare Ombudsman shall, to the*
 21 *extent appropriate, coordinate with State med-*
 22 *ical Ombudsman programs, and with State- and*
 23 *community-based consumer organizations, to—*

24 *“(i) provide information about the*
 25 *medicare program; and*

1 “(ii) *conduct outreach to educate medi-*
 2 *care beneficiaries with respect to manners*
 3 *in which problems under the medicare pro-*
 4 *gram may be resolved or avoided.*

5 “(e) *MEDICARE COMPETITIVE POLICY ADVISORY*
 6 *BOARD.—*

7 “(1) *ESTABLISHMENT.—There is established*
 8 *within the Center for Medicare Choices the Medicare*
 9 *Competitive Policy Advisory Board (in this section*
 10 *referred to as the ‘Board’). The Board shall advise,*
 11 *consult with, and make recommendations to the Ad-*
 12 *ministrator with respect to the administration of*
 13 *parts C and D, including the review of payment poli-*
 14 *cies under such parts.*

15 “(2) *REPORTS.—*

16 “(A) *IN GENERAL.—With respect to matters*
 17 *of the administration of parts C and D, the*
 18 *Board shall submit to Congress and to the Ad-*
 19 *ministrator such reports as the Board determines*
 20 *appropriate. Each such report may contain such*
 21 *recommendations as the Board determines ap-*
 22 *propriate for legislative or administrative*
 23 *changes to improve the administration of such*
 24 *parts, including the stability and solvency of the*
 25 *programs under such parts and the topics de-*

1 scribed in subparagraph (B). Each such report
2 shall be published in the Federal Register.

3 “(B) TOPICS DESCRIBED.—Reports required
4 under subparagraph (A) may include the fol-
5 lowing topics:

6 “(i) FOSTERING COMPETITION.—Rec-
7 ommendations or proposals to increase com-
8 petition under parts C and D for services
9 furnished to medicare beneficiaries.

10 “(ii) EDUCATION AND ENROLLMENT.—
11 Recommendations for the improvement of
12 efforts to provide medicare beneficiaries in-
13 formation and education on the program
14 under this title, and specifically parts C
15 and D, and the program for enrollment
16 under the title.

17 “(iii) QUALITY.—Recommendations on
18 ways to improve the quality of benefits pro-
19 vided under plans under parts C and D.

20 “(iv) DISEASE MANAGEMENT PRO-
21 GRAMS.—Recommendations on the incorpo-
22 ration of disease management programs
23 under parts C and D.

1 “(v) *RURAL ACCESS.*—*Recommendations to improve competition and access to*
 2 *plans under parts C and D in rural areas.*

4 “(C) *MAINTAINING INDEPENDENCE OF*
 5 *BOARD.*—*The Board shall directly submit to*
 6 *Congress reports required under subparagraph*
 7 *(A). No officer or agency of the United States*
 8 *may require the Board to submit to any officer*
 9 *or agency of the United States for approval,*
 10 *comments, or review, prior to the submission to*
 11 *Congress of such reports.*

12 “(3) *DUTY OF ADMINISTRATOR.*—*With respect to*
 13 *any report submitted by the Board under paragraph*
 14 *(2)(A), not later than 90 days after the report is sub-*
 15 *mitted, the Administrator shall submit to Congress*
 16 *and the President an analysis of recommendations*
 17 *made by the Board in such report. Each such anal-*
 18 *ysis shall be published in the Federal Register.*

19 “(4) *MEMBERSHIP.*—

20 “(A) *APPOINTMENT.*—*Subject to the suc-*
 21 *ceeding provisions of this paragraph, the Board*
 22 *shall consist of 7 members to be appointed as fol-*
 23 *lows:*

24 “(i) *Three members shall be appointed*
 25 *by the President.*

1 “(ii) *Two members shall be appointed*
 2 *by the Speaker of the House of Representa-*
 3 *tives, with the advice of the chairman and*
 4 *the ranking minority member of the Com-*
 5 *mittees on Ways and Means and on Energy*
 6 *and Commerce of the House of Representa-*
 7 *tives.*

8 “(iii) *Two members shall be appointed*
 9 *by the President pro tempore of the Senate*
 10 *with the advice of the chairman and the*
 11 *ranking minority member of the Committee*
 12 *on Finance of the Senate.*

13 “(B) *QUALIFICATIONS.—The members shall*
 14 *be chosen on the basis of their integrity, impar-*
 15 *tiality, and good judgment, and shall be individ-*
 16 *uals who are, by reason of their education and*
 17 *experience in health care benefits management,*
 18 *exceptionally qualified to perform the duties of*
 19 *members of the Board.*

20 “(C) *PROHIBITION ON INCLUSION OF FED-*
 21 *ERAL EMPLOYEES.—No officer or employee of the*
 22 *United States may serve as a member of the*
 23 *Board.*

24 “(5) *COMPENSATION.—Members of the Board*
 25 *shall receive, for each day (including travel time) they*

1 *are engaged in the performance of the functions of the*
 2 *Board, compensation at rates not to exceed the daily*
 3 *equivalent to the annual rate in effect for level IV of*
 4 *the Executive Schedule under section 5315 of title 5,*
 5 *United States Code.*

6 “(6) *TERMS OF OFFICE.*—

7 “(A) *IN GENERAL.*—*The term of office of*
 8 *members of the Board shall be 3 years.*

9 “(B) *TERMS OF INITIAL APPOINTEES.*—*As*
 10 *designated by the President at the time of ap-*
 11 *pointment, of the members first appointed—*

12 “(i) *one shall be appointed for a term*
 13 *of 1 year;*

14 “(ii) *three shall be appointed for terms*
 15 *of 2 years; and*

16 “(iii) *three shall be appointed for*
 17 *terms of 3 years.*

18 “(C) *REAPPOINTMENTS.*—*Any person ap-*
 19 *pointed as a member of the Board may not serve*
 20 *for more than 8 years.*

21 “(D) *VACANCY.*—*Any member appointed to*
 22 *fill a vacancy occurring before the expiration of*
 23 *the term for which the member’s predecessor was*
 24 *appointed shall be appointed only for the re-*
 25 *mainder of that term. A member may serve after*

1 *the expiration of that member's term until a suc-*
 2 *cessor has taken office. A vacancy in the Board*
 3 *shall be filled in the manner in which the origi-*
 4 *nal appointment was made.*

5 “(7) *CHAIR.—The Chair of the Board shall be*
 6 *elected by the members. The term of office of the Chair*
 7 *shall be 3 years.*

8 “(8) *MEETINGS.—The Board shall meet at the*
 9 *call of the Chair, but in no event less than 3 times*
 10 *during each fiscal year.*

11 “(9) *DIRECTOR AND STAFF.—*

12 “(A) *APPOINTMENT OF DIRECTOR.—The*
 13 *Board shall have a Director who shall be ap-*
 14 *pointed by the Chair.*

15 “(B) *IN GENERAL.—With the approval of*
 16 *the Board, the Director may appoint such addi-*
 17 *tional personnel as the Director considers appro-*
 18 *priate.*

19 “(C) *ASSISTANCE FROM THE ADMINIS-*
 20 *TRATOR.—The Administrator shall make avail-*
 21 *able to the Board such information and other as-*
 22 *sistance as it may require to carry out its func-*
 23 *tions.*

24 “(10) *CONTRACT AUTHORITY.—The Board may*
 25 *contract with and compensate government and pri-*

1 *vate agencies or persons to carry out its duties under*
 2 *this subsection, without regard to section 3709 of the*
 3 *Revised Statutes (41 U.S.C. 5).*

4 “(f) *FUNDING.*—*There is authorized to be appro-*
 5 *priated, in appropriate part from the Federal Hospital In-*
 6 *surance Trust Fund and from the Federal Supplementary*
 7 *Medical Insurance Trust Fund (including the Prescription*
 8 *Drug Account), such sums as are necessary to carry out*
 9 *this section.”.*

10 (b) *USE OF CENTRAL, TOLL-FREE NUMBER (1-800-*
 11 *MEDICARE).*—*Section 1804(b) (42 U.S.C. 1395b-2(b)) is*
 12 *amended by adding at the end the following: “By not later*
 13 *than 1 year after the date of the enactment of the Prescrip-*
 14 *tion Drug and Medicare Improvement Act of 2003, the Sec-*
 15 *retary shall provide, through the toll-free number 1-800-*
 16 *MEDICARE, for a means by which individuals seeking in-*
 17 *formation about, or assistance with, such programs who*
 18 *phone such toll-free number are transferred (without*
 19 *charge) to appropriate entities for the provision of such in-*
 20 *formation or assistance. Such toll-free number shall be the*
 21 *toll-free number listed for general information and assist-*
 22 *ance in the annual notice under subsection (a) instead of*
 23 *the listing of numbers of individual contractors.”.*

1 **SEC. 302. MISCELLANEOUS ADMINISTRATIVE PROVISIONS.**

2 (a) *ADMINISTRATOR AS MEMBER AND CO-SECRETARY*
 3 *OF THE BOARD OF TRUSTEES OF THE MEDICARE TRUST*
 4 *FUNDS.*—*The fifth sentence of sections 1817(b) and 1841(b)*
 5 *(42 U.S.C. 1395i(b), 1395t(b)) are each amended by strik-*
 6 *ing “shall serve as the Secretary” and inserting “and the*
 7 *Administrator of the Center for Medicare Choices shall serve*
 8 *as the Co-Secretaries”.*

9 (b) *INCREASE IN GRADE TO EXECUTIVE LEVEL III*
 10 *FOR THE ADMINISTRATOR OF THE CENTERS FOR MEDI-*
 11 *CARE & MEDICAID SERVICES.*—

12 (1) *IN GENERAL.*—*Section 5314 of title 5,*
 13 *United States Code, is amended by adding at the end*
 14 *the following:*

15 *“Administrator of the Centers for Medicare &*
 16 *Medicaid Services.”.*

17 (2) *CONFORMING AMENDMENT.*—*Section 5315 of*
 18 *such title is amended by striking “Administrator of*
 19 *the Health Care Financing Administration.”.*

20 (3) *EFFECTIVE DATE.*—*The amendments made*
 21 *by this subsection take effect on March 1, 2004.*

1 ***TITLE IV—MEDICARE FEE-FOR-***
 2 ***SERVICE IMPROVEMENTS***
 3 ***Subtitle A—Provisions Relating to***
 4 ***Part A***

5 ***SEC. 401. EQUALIZING URBAN AND RURAL STANDARDIZED***
 6 ***PAYMENT AMOUNTS UNDER THE MEDICARE***
 7 ***INPATIENT HOSPITAL PROSPECTIVE PAY-***
 8 ***MENT SYSTEM.***

9 *(a) IN GENERAL.—Section 1886(d)(3)(A)(iv) (42*
 10 *U.S.C. 1395ww(d)(3)(A)(iv)) is amended—*

11 *(1) by striking “(iv) For discharges” and insert-*
 12 *ing “(iv)(I) Subject to subclause (II), for discharges”;*
 13 *and*

14 *(2) by adding at the end the following new sub-*
 15 *clause:*

16 *“(II) For discharges occurring in a fiscal year*
 17 *(beginning with fiscal year 2004), the Secretary shall*
 18 *compute a standardized amount for hospitals located*
 19 *in any area within the United States and within*
 20 *each region equal to the standardized amount com-*
 21 *puted for the previous fiscal year under this subpara-*
 22 *graph for hospitals located in a large urban area (or,*
 23 *beginning with fiscal year 2005, for applicable for all*
 24 *hospitals in the previous fiscal year) increased by the*

1 *applicable percentage increase under subsection*
 2 *(b)(3)(B)(i) for the fiscal year involved.”.*

3 *(b) APPLICATION TO SUBSECTION (D) PUERTO RICO*
 4 *HOSPITALS.—Section 1886(d)(9) (42 U.S.C.*
 5 *1395ww(d)(9)) is amended—*

6 *(1) in subparagraph (A)—*

7 *(A) in clause (i), by striking “and” after*
 8 *the comma at the end;*

9 *(B) in clause (ii)—*

10 *(i) in the matter preceding subclause*
 11 *(I), by inserting “and before October 1,*
 12 *2003” after “October 1, 1997”; and*

13 *(ii) in the matter following clause*
 14 *(III), by striking the period at the end and*
 15 *inserting “, and”; and*

16 *(iii) by adding at the end the following*
 17 *new clause:*

18 *“(iii) for discharges in a fiscal year beginning*
 19 *on or after October 1, 2003, 50 percent of the national*
 20 *standardized rate (determined under paragraph*
 21 *(3)(D)(iii)) for hospitals located in any area.”;*

22 *(2) in subparagraph (C)—*

23 *(A) in clause (i)—*

24 *(i) by striking “(i) The Secretary” and*
 25 *inserting “(i)(I) For discharges in a fiscal*

1 year after fiscal year 1988 and before fiscal
2 year 2004, the Secretary; and

3 (ii) by adding at the end the following:

4 “(II) For discharges in fiscal year 2004, the Sec-
5 retary shall compute an average standardized amount
6 for hospitals located in any area of Puerto Rico that
7 is equal to the average standardized amount com-
8 puted under subclause (I) for fiscal year 2003 for hos-
9 pitals in an urban area, increased by the applicable
10 percentage increase under subsection (b)(3)(B) for fis-
11 cal year 2004.

12 “(III) For discharges in a fiscal year after fiscal
13 year 2004, the Secretary shall compute an average
14 standardized amount for hospitals located in any are
15 of Puerto Rico that is equal to the average standard-
16 ized amount computed under subclause (II) or this
17 subclause for the previous fiscal year, increased by the
18 applicable percentage increase under subsection
19 (b)(3)(B), adjusted to reflect the most recent case mix
20 data.”;

21 (B) in clause (ii), by inserting “(or for fis-
22 cal year 2004 and thereafter, the standardized
23 amount)” after “each of the average standardized
24 amounts”; and

1 (C) in clause (iii)(I), by striking “for hos-
 2 pitals located in an urban or rural area, respec-
 3 tively”.

4 (c) CONFORMING AMENDMENTS.—

5 (1) COMPUTING DRG-SPECIFIC RATES.—Section
 6 1886(d)(3)(D) (42 U.S.C. 1395ww(d)(3)(D)) is
 7 amended—

8 (A) in the heading, by striking “IN DIF-
 9 FERENT AREAS”;

10 (B) in the matter preceding clause (i), by
 11 striking “, each of”;

12 (C) in clause (i)—

13 (i) in the matter preceding subclause
 14 (I), by inserting “for fiscal years before fis-
 15 cal year 2004,” before “for hospitals”; and

16 (ii) in subclause (II), by striking
 17 “and” after the semicolon at the end;

18 (D) in clause (ii)—

19 (i) in the matter preceding subclause
 20 (I), by inserting “for fiscal years before fis-
 21 cal year 2004,” before “for hospitals”; and

22 (ii) in subclause (II), by striking the
 23 period at the end and inserting “; and”;
 24 and

1 (E) by adding at the end the following new
2 *clause:*

3 “(iii) for a fiscal year beginning after fiscal
4 year 2003, for hospitals located in all areas, to
5 the product of—

6 “(I) the applicable standardized
7 amount (computed under subparagraph
8 (A)), reduced under subparagraph (B), and
9 adjusted or reduced under subparagraph (C)
10 for the fiscal year; and

11 “(II) the weighting factor (determined
12 under paragraph (4)(B)) for that diagnosis-
13 related group.”.

14 (2) *TECHNICAL CONFORMING SUNSET.*—Section
15 1886(d)(3) (42 U.S.C. 1395ww(d)(3)) is amended—

16 (A) in the matter preceding subparagraph
17 (A), by inserting “, for fiscal years before fiscal
18 year 1997,” before “a regional adjusted DRG
19 prospective payment rate”; and

20 (B) in subparagraph (D), in the matter
21 preceding clause (i), by inserting “, for fiscal
22 years before fiscal year 1997,” before “a regional
23 DRG prospective payment rate for each region,”.

1 **SEC. 402. ADJUSTMENT TO THE MEDICARE INPATIENT HOS-**
 2 **PITAL PPS WAGE INDEX TO REVISE THE**
 3 **LABOR-RELATED SHARE OF SUCH INDEX.**

4 (a) *IN GENERAL.*—Section 1886(d)(3)(E) (42 U.S.C.
 5 1395ww(d)(3)(E)) is amended—

6 (1) by striking “WAGE LEVELS.—The Secretary”
 7 and inserting “WAGE LEVELS.—

8 “(i) *IN GENERAL.*—Except as provided in
 9 clause (ii), the Secretary”; and

10 (2) by adding at the end the following new
 11 clause:

12 “(ii) *ALTERNATIVE PROPORTION TO BE AD-*
 13 *JUSTED BEGINNING IN FISCAL YEAR 2005.*—

14 “(I) *IN GENERAL.*—Except as provided
 15 in subclause (II), for discharges occurring
 16 on or after October 1, 2004, the Secretary
 17 shall substitute ‘62 percent’ for the propor-
 18 tion described in the first sentence of clause
 19 (i).

20 “(II) *HOLD HARMLESS FOR CERTAIN*
 21 *HOSPITALS.*—If the application of subclause
 22 (I) would result in lower payments to a hos-
 23 pital than would otherwise be made, then
 24 this subparagraph shall be applied as if this
 25 clause had not been enacted.”.

1 (b) *WAIVING BUDGET NEUTRALITY.*—Section
 2 1886(d)(3)(E) (42 U.S.C. 1395ww(d)(3)(E)), as amended
 3 by subsection (a), is amended by adding at the end of clause
 4 (i) the following new sentence: “The Secretary shall apply
 5 the previous sentence for any period as if the amendments
 6 made by section 402(a) of the Prescription Drug and Medi-
 7 care Improvement Act of 2003 had not been enacted.”.

8 **SEC. 403. MEDICARE INPATIENT HOSPITAL PAYMENT AD-**
 9 **JUSTMENT FOR LOW-VOLUME HOSPITALS.**

10 Section 1886(d) (42 U.S.C. 1395ww(d)) is amended by
 11 adding at the end the following new paragraph:

12 “(12) *PAYMENT ADJUSTMENT FOR LOW-VOLUME*
 13 *HOSPITALS.*—

14 “(A) *PAYMENT ADJUSTMENT.*—

15 “(i) *IN GENERAL.*—Notwithstanding
 16 any other provision of this section, for each
 17 cost reporting period (beginning with the
 18 cost reporting period that begins in fiscal
 19 year 2005), the Secretary shall provide for
 20 an additional payment amount to each low-
 21 volume hospital (as defined in clause (iii))
 22 for discharges occurring during that cost re-
 23 porting period which is equal to the appli-
 24 cable percentage increase (determined under

1 *clause (ii)) in the amount paid to such hos-*
2 *pital under this section for such discharges.*

3 “(ii) *APPLICABLE PERCENTAGE IN-*
4 *CREASE.—The Secretary shall determine a*
5 *percentage increase applicable under this*
6 *paragraph that ensures that—*

7 “(I) *no percentage increase in*
8 *payments under this paragraph ex-*
9 *ceeds 25 percent of the amount of pay-*
10 *ment that would (but for this para-*
11 *graph) otherwise be made to a low-vol-*
12 *ume hospital under this section for*
13 *each discharge;*

14 “(II) *low-volume hospitals that*
15 *have the lowest number of discharges*
16 *during a cost reporting period receive*
17 *the highest percentage increases in*
18 *payments due to the application of this*
19 *paragraph; and*

20 “(III) *the percentage increase in*
21 *payments to any low-volume hospital*
22 *due to the application of this para-*
23 *graph is reduced as the number of dis-*
24 *charges per cost reporting period in-*
25 *creases.*

1 “(iii) *LOW-VOLUME HOSPITAL DE-*
 2 *FINED.*—For purposes of this paragraph,
 3 the term ‘low-volume hospital’ means, for a
 4 cost reporting period, a subsection (d) hos-
 5 pital (as defined in paragraph (1)(B)) other
 6 than a critical access hospital (as defined in
 7 section 1861(mm)(1)) that—

8 “(I) the Secretary determines had
 9 an average of less than 2,000 dis-
 10 charges (determined with respect to all
 11 patients and not just individuals re-
 12 ceiving benefits under this title) during
 13 the 3 most recent cost reporting periods
 14 for which data are available that pre-
 15 cede the cost reporting period to which
 16 this paragraph applies; and

17 “(II) is located at least 15 miles
 18 from a like hospital (or is deemed by
 19 the Secretary to be so located by reason
 20 of such factors as the Secretary deter-
 21 mines appropriate, including the time
 22 required for an individual to travel to
 23 the nearest alternative source of appro-
 24 priate inpatient care (after taking into
 25 account the location of such alternative

source of inpatient care and any weather or travel conditions that may affect such travel time).

“(B) *PROHIBITING CERTAIN REDUCTIONS.*—

Notwithstanding subsection (e), the Secretary shall not reduce the payment amounts under this section to offset the increase in payments resulting from the application of subparagraph (A).”.

SEC. 404. FAIRNESS IN THE MEDICARE DISPROPORTIONATE SHARE HOSPITAL (DSH) ADJUSTMENT FOR RURAL HOSPITALS.

(a) *EQUALIZING DSH PAYMENT AMOUNTS.*—

(1) *IN GENERAL.*—Section 1886(d)(5)(F)(vii) (42 U.S.C. 1395ww(d)(5)(F)(vii)) is amended by inserting “, and, after October 1, 2004, for any other hospital described in clause (iv),” after “clause (iv)(I)” in the matter preceding subclause (I).

(2) *CONFORMING AMENDMENTS.*—Section 1886(d)(5)(F) (42 U.S.C. 1395ww(d)(5)(F)) is amended—

(A) in clause (iv)—

(i) in subclause (II)—

(I) by inserting “and before October 1, 2004,” after “April 1, 2001,”; and

1 (II) by inserting “or, for dis-
 2 charges occurring on or after October
 3 1, 2004, is equal to the percent deter-
 4 mined in accordance with the applica-
 5 ble formula described in clause (vii)”
 6 after “clause (xiii)”;

7 (ii) in subclause (III)—

8 (I) by inserting “and before Octo-
 9 ber 1, 2004,” after “April 1, 2001,”;
 10 and

11 (II) by inserting “or, for dis-
 12 charges occurring on or after October
 13 1, 2004, is equal to the percent deter-
 14 mined in accordance with the applica-
 15 ble formula described in clause (vii)”
 16 after “clause (xii)”;

17 (iii) in subclause (IV)—

18 (I) by inserting “and before Octo-
 19 ber 1, 2004,” after “April 1, 2001,”;
 20 and

21 (II) by inserting “or, for dis-
 22 charges occurring on or after October
 23 1, 2004, is equal to the percent deter-
 24 mined in accordance with the applica-

1 *ble formula described in clause (vii)”*

2 *after “clause (x) or (xi)”;*

3 *(iv) in subclause (V)—*

4 *(I) by inserting “and before Octo-*

5 *ber 1, 2004,” after “April 1, 2001,”;*

6 *and*

7 *(II) by inserting “or, for dis-*

8 *charges occurring on or after October*

9 *1, 2004, is equal to the percent deter-*

10 *mined in accordance with the applica-*

11 *ble formula described in clause (vii)”*

12 *after “clause (xi)”;* and

13 *(v) in subclause (VI)—*

14 *(I) by inserting “and before Octo-*

15 *ber 1, 2004,” after “April 1, 2001,”;*

16 *and*

17 *(II) by inserting “or, for dis-*

18 *charges occurring on or after October*

19 *1, 2004, is equal to the percent deter-*

20 *mined in accordance with the applica-*

21 *ble formula described in clause (vii)”*

22 *after “clause (x)”;*

23 *(B) in clause (viii), by striking “The for-*

24 *mula” and inserting “For discharges occurring*

25 *before October 1, 2004, the formula”;* and

1 (C) in each of clauses (x), (xi), (xii), and
 2 (xiii), by striking “For purposes” and inserting
 3 “With respect to discharges occurring before Oc-
 4 tober 1, 2004, for purposes”.

5 (b) *EFFECTIVE DATE.*—The amendments made by this
 6 section shall apply to discharges occurring on or after Octo-
 7 ber 1, 2004.

8 **SEC. 404A. MEDPAC STUDY AND REPORT REGARDING MEDI-**
 9 **CARE DISPROPORTIONATE SHARE HOSPITAL**
 10 **(DSH) ADJUSTMENT PAYMENTS.**

11 (a) *STUDY.*—The Medicare Payment Advisory Com-
 12 mission established under section 1805 of the Social Secu-
 13 rity Act (42 U.S.C. 1395b–6) (in this section referred to
 14 as “MedPAC”) shall conduct a study to determine, with re-
 15 spect to additional payment amounts paid to subsection (d)
 16 hospitals under section 1886(d)(5)(F) of the Social Security
 17 Act (42 U.S.C. 1395ww(d)(5)(F))—

18 (1) whether such payments should be made in the
 19 same manner as payments are made with respect to
 20 graduate medical education under title XVIII and
 21 with respect to hospitals that serve a disproportionate
 22 share of low-income patients under the medicaid pro-
 23 gram; and

1 (2) *whether to add costs attributable to uncom-*
 2 *pensated care to the formula for determining such*
 3 *payment amounts.*

4 (b) *REPORT.*—*Not later than 1 year after the date of*
 5 *enactment of this Act, MedPAC shall submit a report to*
 6 *Congress on the study conducted under subsection (a), to-*
 7 *gether with such recommendations for legislation as*
 8 *MedPAC determines are appropriate.*

9 **SEC. 405. CRITICAL ACCESS HOSPITAL (CAH) IMPROVE-**
 10 **MENTS.**

11 (a) *PERMITTING CAHS TO ALLOCATE SWING BEDS*
 12 *AND ACUTE CARE INPATIENT BEDS SUBJECT TO A TOTAL*
 13 *LIMIT OF 25 BEDS.*—

14 (1) *IN GENERAL.*—*Section 1820(c)(2)(B)(iii) (42*
 15 *U.S.C. 1395i–4(c)(2)(B)(iii)) is amended to read as*
 16 *follows:*

17 *“(iii) provides not more than a total of*
 18 *25 extended care service beds (pursuant to*
 19 *an agreement under subsection (f)) and*
 20 *acute care inpatient beds (meeting such*
 21 *standards as the Secretary may establish)*
 22 *for providing inpatient care for a period*
 23 *that does not exceed, as determined on an*
 24 *annual, average basis, 96 hours per pa-*
 25 *tient;”.*

1 (2) *CONFORMING AMENDMENT.*—Section 1820(f)
 2 (42 U.S.C. 1395i–4(f)) is amended by striking “and
 3 the number of beds used at any time for acute care
 4 inpatient services does not exceed 15 beds”.

5 (3) *EFFECTIVE DATE.*—The amendments made
 6 by this subsection shall with respect to designations
 7 made on or after October 1, 2004.

8 (b) *ELIMINATION OF THE ISOLATION TEST FOR COST-*
 9 *BASED CAH AMBULANCE SERVICES.*—

10 (1) *ELIMINATION.*—

11 (A) *IN GENERAL.*—Section 1834(l)(8) (42
 12 U.S.C. 1395m(l)(8)), as added by section 205(a)
 13 of BIPA (114 Stat. 2763A–482), is amended by
 14 striking the comma at the end of subparagraph
 15 (B) and all that follows and inserting a period.

16 (B) *EFFECTIVE DATE.*—The amendment
 17 made by subparagraph (A) shall apply to serv-
 18 ices furnished on or after January 1, 2005.

19 (2) *TECHNICAL CORRECTION.*—Section 1834(l)
 20 (42 U.S.C. 1395m(l)) is amended by redesignating
 21 paragraph (8), as added by section 221(a) of BIPA
 22 (114 Stat. 2763A–486), as paragraph (9).

23 (c) *COVERAGE OF COSTS FOR CERTAIN EMERGENCY*
 24 *ROOM ON-CALL PROVIDERS.*—

1 (1) *IN GENERAL*.—Section 1834(g)(5) (42 U.S.C.
2 1395m(g)(5)) is amended—

3 (A) in the heading—

4 (i) by inserting “CERTAIN” before
5 “EMERGENCY”; and

6 (ii) by striking “PHYSICIANS” and in-
7 serting “PROVIDERS”;

8 (B) by striking “emergency room physicians
9 who are on-call (as defined by the Secretary)”
10 and inserting “physicians, physician assistants,
11 nurse practitioners, and clinical nurse specialists
12 who are on-call (as defined by the Secretary) to
13 provide emergency services”; and

14 (C) by striking “physicians’ services” and
15 inserting “services covered under this title”.

16 (2) *EFFECTIVE DATE*.—The amendments made
17 by paragraph (1) shall apply to costs incurred for
18 services provided on or after January 1, 2005.

19 (d) *AUTHORIZATION OF PERIODIC INTERIM PAYMENT*
20 (PIP).—

21 (1) *IN GENERAL*.—Section 1815(e)(2) (42 U.S.C.
22 1395g(e)(2)) is amended—

23 (A) in subparagraph (C), by striking “and”
24 after the semicolon at the end;

1 (B) in subparagraph (D), by adding “and”
 2 after the semicolon at the end; and

3 (C) by inserting after subparagraph (D) the
 4 following new subparagraph:

5 “(E) inpatient critical access hospital services;”.

6 (2) *EFFECTIVE DATE.*—The amendments made
 7 by paragraph (1) shall apply to payments for inpa-
 8 tient critical access facility services furnished on or
 9 after January 1, 2005.

10 (e) *EXCLUSION OF NEW CAHS FROM PPS HOSPITAL*
 11 *WAGE INDEX CALCULATION.*—Section 1886(d)(3)(E)(i) (42
 12 U.S.C. 1395ww(d)(3)(E)(i)), as amended by section 402, is
 13 amended by inserting after the first sentence the following
 14 new sentence: “In calculating the hospital wage levels under
 15 the preceding sentence applicable with respect to cost report-
 16 ing periods beginning on or after January 1, 2004, the Sec-
 17 retary shall exclude the wage levels of any facility that be-
 18 came a critical access hospital prior to the cost reporting
 19 period for which such hospital wage levels are calculated.”.

20 (f) *PROVISIONS RELATED TO CERTAIN RURAL*
 21 *GRANTS.*—

22 (1) *SMALL RURAL HOSPITAL IMPROVEMENT PRO-*
 23 *GRAM.*—Section 1820(g) (42 U.S.C. 1395i–4(g)) is
 24 amended—

1 (A) by redesignating paragraph (3)(F) as
 2 paragraph (5) and redesignating and indenting
 3 appropriately; and

4 (B) by inserting after paragraph (3) the fol-
 5 lowing new paragraph:

6 “(4) *SMALL RURAL HOSPITAL IMPROVEMENT*
 7 *PROGRAM.*—

8 “(A) *GRANTS TO HOSPITALS.*—*The Sec-*
 9 *retary may award grants to hospitals that have*
 10 *submitted applications in accordance with sub-*
 11 *paragraph (B) to assist eligible small rural hos-*
 12 *pitals (as defined in paragraph (3)(B)) in meet-*
 13 *ing the costs of reducing medical errors, increas-*
 14 *ing patient safety, protecting patient privacy,*
 15 *and improving hospital quality and perform-*
 16 *ance.*

17 “(B) *APPLICATION.*—*A hospital seeking a*
 18 *grant under this paragraph shall submit an ap-*
 19 *plication to the Secretary on or before such date*
 20 *and in such form and manner as the Secretary*
 21 *specifies.*

22 “(C) *AMOUNT OF GRANT.*—*A grant to a*
 23 *hospital under this paragraph may not exceed*
 24 *\$50,000.*

1 “(D) *USE OF FUNDS.*—*A hospital receiving*
 2 *a grant under this paragraph may use the funds*
 3 *for the purchase of computer software and hard-*
 4 *ware, the education and training of hospital*
 5 *staff, and obtaining technical assistance.”.*

6 (2) *AUTHORIZATION FOR APPROPRIATIONS.*—
 7 *Section 1820(j) (42 U.S.C. 1395i–4(j)) is amended to*
 8 *read as follows:*

9 “(j) *AUTHORIZATION OF APPROPRIATIONS.*—

10 “(1) *HI TRUST FUND.*—*There are authorized to*
 11 *be appropriated from the Federal Hospital Insurance*
 12 *Trust Fund for making grants to all States under—*

13 “(A) *subsection (g), \$25,000,000 in each of*
 14 *the fiscal years 1998 through 2002; and*

15 “(B) *paragraphs (1) and (2) of subsection*
 16 *(g), \$40,000,000 in each of the fiscal years 2004*
 17 *through 2008.*

18 “(2) *GENERAL REVENUES.*—*There are authorized*
 19 *to be appropriated from amounts in the Treasury not*
 20 *otherwise appropriated for making grants to all*
 21 *States under subsection (g)(4), \$25,000,000 in each of*
 22 *the fiscal years 2004 through 2008.”.*

23 (3) *REQUIREMENT THAT STATES AWARDED*
 24 *GRANTS CONSULT WITH THE STATE HOSPITAL ASSO-*

1 *CIATION AND RURAL HOSPITALS ON THE MOST APPRO-*
 2 *PRIATE WAYS TO USE SUCH GRANTS.—*

3 (A) *IN GENERAL.—Section 1820(g) (42*
 4 *U.S.C. 1395i–4(g)), as amended by paragraph*
 5 *(1), is amended by adding at the end the fol-*
 6 *lowing new paragraph:*

7 “(6) *REQUIRED CONSULTATION FOR STATES*
 8 *AWARDED GRANTS.—A State awarded a grant under*
 9 *paragraph (1) or (2) shall consult with the hospital*
 10 *association of such State and rural hospitals located*
 11 *in such State on the most appropriate ways to use the*
 12 *funds under such grant.”.*

13 (B) *EFFECTIVE DATE AND APPLICATION.—*
 14 *The amendment made by subparagraph (A) shall*
 15 *take effect on the date of enactment of this Act*
 16 *and shall apply to grants awarded on or after*
 17 *such date and to grants awarded prior to such*
 18 *date to the extent that funds under such grants*
 19 *have not been obligated as of such date.*

20 (g) *EXCLUSION OF CERTAIN BEDS FROM BED COUNT*
 21 *AND REMOVAL OF BARRIERS TO ESTABLISHMENT OF DIS-*
 22 *TINCT PART UNITS.—*

23 (1) *EXCLUSION OF CERTAIN BEDS FROM BED*
 24 *COUNT.—Section 1820(c)(2) (42 U.S.C. 1395i–*

1 4(c)(2)) is amended by adding at the end the fol-
 2 lowing:

3 “(E) *EXCLUSION OF CERTAIN BEDS FROM*
 4 *BED COUNT.*—In determining the number of beds
 5 of a facility for purposes of applying the bed
 6 limitations referred to in subparagraph (B)(iii)
 7 and subsection (f), the Secretary shall not take
 8 into account any bed of a distinct part psy-
 9 chiatric or rehabilitation unit (described in the
 10 matter following clause (v) of section
 11 1886(d)(1)(B)) of the facility, except that the
 12 total number of beds that are not taken into ac-
 13 count pursuant to this subparagraph with re-
 14 spect to a facility shall not exceed 25.”.

15 (2) *REMOVING BARRIERS TO ESTABLISHMENT OF*
 16 *DISTINCT PART UNITS BY CRITICAL ACCESS HOS-*
 17 *PITALS.*—Section 1886(d)(1)(B) (42 U.S.C.
 18 195ww(d)(1)(B)) is amended by striking “a distinct
 19 part of the hospital (as defined by the Secretary)” in
 20 the matter following cause (v) and inserting “a dis-
 21 tinct part (as defined by the Secretary) of the hospital
 22 or of a critical access hospital”.

23 (3) *EFFECTIVE DATE.*—The amendments made
 24 by this subsection shall apply to determinations with
 25 respect to distinct part unit status, and with respect

1 to designations, that are made on or after October 1,
2 2003.

3 **SEC. 406. AUTHORIZING USE OF ARRANGEMENTS TO PRO-**
4 **VIDE CORE HOSPICE SERVICES IN CERTAIN**
5 **CIRCUMSTANCES.**

6 (a) *IN GENERAL.*—Section 1861(dd)(5) (42 U.S.C.
7 1395x(dd)(5)) is amended by adding at the end the fol-
8 lowing:

9 “(D) *In extraordinary, exigent, or other non-routine*
10 *circumstances, such as unanticipated periods of high pa-*
11 *tient loads, staffing shortages due to illness or other events,*
12 *or temporary travel of a patient outside a hospice pro-*
13 *gram’s service area, a hospice program may enter into ar-*
14 *rangements with another hospice program for the provision*
15 *by that other program of services described in paragraph*
16 *(2)(A)(ii)(I). The provisions of paragraph (2)(A)(ii)(II)*
17 *shall apply with respect to the services provided under such*
18 *arrangements.*

19 “(E) *A hospice program may provide services de-*
20 *scribed in paragraph (1)(A) other than directly by the pro-*
21 *gram if the services are highly specialized services of a reg-*
22 *istered professional nurse and are provided non-routinely*
23 *and so infrequently so that the provision of such services*
24 *directly would be impracticable and prohibitively expen-*
25 *sive.”.*

1 (b) *CONFORMING PAYMENT PROVISION.*—Section
 2 1814(i) (42 U.S.C. 1395f(i)) is amended by adding at the
 3 end the following new paragraph:

4 “(4) In the case of hospice care provided by a hospice
 5 program under arrangements under section 1861(dd)(5)(D)
 6 made by another hospice program, the hospice program that
 7 made the arrangements shall bill and be paid for the hospice
 8 care.”.

9 (c) *EFFECTIVE DATE.*—The amendments made by this
 10 section shall apply to hospice care provided on or after Oc-
 11 tober 1, 2004.

12 **SEC. 407. SERVICES PROVIDED TO HOSPICE PATIENTS BY**
 13 **NURSE PRACTITIONERS, CLINICAL NURSE**
 14 **SPECIALISTS, AND PHYSICIAN ASSISTANTS.**

15 (a) *IN GENERAL.*—Section 1812(d)(2)(A) (42 U.S.C.
 16 1395d(d)(2)(A) in the matter following clause (i)(II), is
 17 amended—

18 (1) by inserting “or services described in section
 19 1861(s)(2)(K)” after “except that clause (i) shall not
 20 apply to physicians’ services”; and

21 (2) by inserting “, or by a physician assistant,
 22 nurse practitioner, or clinical nurse specialist whom
 23 is not an employee of the hospice program, and who
 24 the individual identifies as the health care provider
 25 having the most significant role in the determination

1 *and delivery of medical care to the individual at the*
 2 *time the individual makes an election to receive hos-*
 3 *pice care,” after the “(if not an employee of the hos-*
 4 *pice program)”.*

5 *(b) PERMITTING NURSE PRACTITIONERS, PHYSICIAN*
 6 *ASSISTANTS, AND CLINICAL NURSE SPECIALIST TO REVIEW*
 7 *HOSPICE PLANS OF CARE.—Section 1814(a)(7)(B) is*
 8 *amended by inserting “(or by a physician assistant, nurse*
 9 *practitioner or clinical nurse specialist who is not an em-*
 10 *ployee of the hospice program, and whom the individual*
 11 *identifies as the health care provider having the most sig-*
 12 *nificant role in the determination and delivery of medical*
 13 *care to the individual at the time the individual makes an*
 14 *election to receive hospice care)” after “and is periodically*
 15 *reviewed by the individual’s attending physician”.*

16 *(c) EFFECTIVE DATE.—The amendments made by this*
 17 *section shall apply to hospice care furnished on or after Oc-*
 18 *tober 1, 2004.*

19 **SEC. 408. AUTHORITY TO INCLUDE COSTS OF TRAINING OF**
 20 **PSYCHOLOGISTS IN PAYMENTS TO HOS-**
 21 **PITALS UNDER MEDICARE.**

22 *Effective for cost reporting periods beginning on or*
 23 *after October 1, 2004, for purposes of payments to hospitals*
 24 *under the medicare program under title XVIII of the Social*
 25 *Security Act for costs of approved educational activities (as*

1 *defined in section 413.85 of title 42 of the Code of Federal*
 2 *Regulations), such approved educational activities shall in-*
 3 *clude professional educational training programs, recog-*
 4 *nized by the Secretary, for psychologists.*

5 **SEC. 409. REVISION OF FEDERAL RATE FOR HOSPITALS IN**
 6 **PUERTO RICO.**

7 *Section 1886(d)(9) (42 U.S.C. 1395ww(d)(9)) is*
 8 *amended—*

9 *(1) in subparagraph (A)—*

10 *(A) in clause (i), by striking “for discharges*
 11 *beginning on or after October 1, 1997, 50 percent*
 12 *(and for discharges between October 1, 1987, and*
 13 *September 30, 1997, 75 percent)” and inserting*
 14 *“the applicable Puerto Rico percentage (specified*
 15 *in subparagraph (E))”; and*

16 *(B) in clause (ii), by striking “for dis-*
 17 *charges beginning in a fiscal year beginning on*
 18 *or after October 1, 1997, 50 percent (and for dis-*
 19 *charges between October 1, 1987, and September*
 20 *30, 1997, 25 percent)” and inserting “the appli-*
 21 *cable Federal percentage (specified in subpara-*
 22 *graph (E))”; and*

23 *(2) by adding at the end the following new sub-*
 24 *paragraph:*

1 “(E) For purposes of subparagraph (A), for discharges
2 occurring—

3 “(i) between October 1, 1987, and September 30,
4 1997, the applicable Puerto Rico percentage is 75 per-
5 cent and the applicable Federal percentage is 25 per-
6 cent;

7 “(ii) on or after October 1, 1997, and before Oc-
8 tober 1, 2004, the applicable Puerto Rico percentage
9 is 50 percent and the applicable Federal percentage is
10 50 percent;

11 “(iii) on or after October 1, 2004, and before Oc-
12 tober 1, 2009, the applicable Puerto Rico percentage
13 is 0 percent and the applicable Federal percentage is
14 100 percent; and

15 “(iv) on or after October 1, 2009, the applicable
16 Puerto Rico percentage is 50 percent and the applica-
17 ble Federal percentage is 50 percent.”.

18 **SEC. 410. EXCEPTION TO INITIAL RESIDENCY PERIOD FOR**
19 **GERIATRIC RESIDENCY OR FELLOWSHIP PRO-**
20 **GRAMS.**

21 (a) *CLARIFICATION OF CONGRESSIONAL INTENT.*—
22 Congress intended section 1886(h)(5)(F)(ii) of the Social
23 Security Act (42 U.S.C. 1395ww(h)(5)(F)(ii)), as added by
24 section 9202 of the Consolidated Omnibus Budget Reconcili-
25 ation Act of 1985 (Public Law 99–272), to provide an ex-

1 ception to the initial residency period for geriatric resi-
 2 dency or fellowship programs such that, where a particular
 3 approved geriatric training program requires a resident to
 4 complete 2 years of training to initially become board eligi-
 5 ble in the geriatric specialty, the 2 years spent in the geri-
 6 atric training program are treated as part of the resident's
 7 initial residency period, but are not counted against any
 8 limitation on the initial residency period.

9 (b) *INTERIM FINAL REGULATORY AUTHORITY AND EF-*
 10 *FECTIVE DATE.*—The Secretary shall promulgate interim
 11 final regulations consistent with the congressional intent ex-
 12 pressed in this section after notice and pending opportunity
 13 for public comment to be effective for cost reporting periods
 14 beginning on or after October 1, 2003.

15 **SEC. 411. CLARIFICATION OF CONGRESSIONAL INTENT RE-**
 16 **GARDING THE COUNTING OF RESIDENTS IN A**
 17 **NONPROVIDER SETTING AND A TECHNICAL**
 18 **AMENDMENT REGARDING THE 3-YEAR ROLL-**
 19 **ING AVERAGE AND THE IME RATIO.**

20 (a) *CLARIFICATION OF REQUIREMENTS FOR COUNTING*
 21 *RESIDENTS TRAINING IN NONPROVIDER SETTING.*—

22 (1) *D-GME.*—Section 1886(h)(4)(E) (42 U.S.C.
 23 1395ww(h)(4)(E)) is amended by adding at the end
 24 the following new sentence: For purposes of the pre-
 25 ceding sentence time shall only be counted from the ef-

1 *fective date of a written agreement between the hos-*
 2 *pital and the entity owning or operating a nonpro-*
 3 *vider setting. The effective date of such written agree-*
 4 *ment shall be determined in accordance with gen-*
 5 *erally accepted accounting principles. All, or substan-*
 6 *tially all, of the costs for the training program in*
 7 *that setting shall be defined as the residents' stipends*
 8 *and benefits and other costs, if any, as determined by*
 9 *the parties.”.*

10 (2) *IME*.—Section 1886(d)(5)(B)(iv) (42 U.S.C.
 11 1395ww(d)(5)(B)(iv)) is amended by adding at the
 12 end the following new sentence: *For purposes of the*
 13 *preceding sentence time shall only be counted from the*
 14 *effective date of a written agreement between the hos-*
 15 *pital and the entity owning or operating a nonpro-*
 16 *vider setting. The effective date of such written agree-*
 17 *ment shall be determined in accordance with gen-*
 18 *erally accepted accounting principles. All, or substan-*
 19 *tially all, of the costs for the training program in*
 20 *that setting shall be defined as the residents' stipends*
 21 *and benefits and other costs, if any, as determined by*
 22 *the parties.”.*

23 (b) *LIMITING ONE-YEAR LAG IN THE INDIRECT MED-*
 24 *ICAL EDUCATION (IME) RATIO AND THREE-YEAR ROLLING*
 25 *AVERAGE IN RESIDENT COUNT FOR IME AND FOR DIRECT*

1 *GRADUATE MEDICAL EDUCATION (D–GME) TO MEDICAL*
 2 *RESIDENCY PROGRAMS.—*

3 (1) *IME RATIO AND IME ROLLING AVERAGE.—*

4 *Section 1886(d)(5)(B)(vi) of the Social Security Act*
 5 *(42 U.S.C. 1395ww(d)(5)(B)(vi)) is amended by add-*
 6 *ing at the end the following new sentence: “For cost*
 7 *reporting periods beginning during fiscal years begin-*
 8 *ning on or after October 1, 2004, subclauses (I) and*
 9 *(II) shall be applied only with respect to a hospital’s*
 10 *approved medical residency training programs in the*
 11 *fields of allopathic and osteopathic medicine.”.*

12 (2) *D–GME ROLLING AVERAGE.—Section*
 13 *1886(h)(4)(G) of the Social Security Act (42 U.S.C.*
 14 *1395ww(h)(4)(G)) is amended by adding at the end*
 15 *the following new clause:*

16 *“(iv) APPLICATION FOR FISCAL YEAR*
 17 *2004 AND SUBSEQUENT YEARS.—For cost re-*
 18 *porting periods beginning during fiscal*
 19 *years beginning on or after October 1, 2004,*
 20 *clauses (i) through (iii) shall be applied*
 21 *only with respect to a hospital’s approved*
 22 *medical residency training program in the*
 23 *fields of allopathic and osteopathic medi-*
 24 *cine.”.*

1 **SEC. 412. LIMITATION ON CHARGES FOR INPATIENT HOS-**
 2 **PITAL CONTRACT HEALTH SERVICES PRO-**
 3 **VIDED TO INDIANS BY MEDICARE PARTICI-**
 4 **PATING HOSPITALS.**

5 (a) *IN GENERAL.*—Section 1866(a)(1) (42 U.S.C.
 6 1395cc(a)(1)) is amended—

7 (1) *in subparagraph (R), by striking “and” at*
 8 *the end;*

9 (2) *in subparagraph (S), by striking the period*
 10 *and inserting “, and”; and*

11 (3) *by adding at the end the following new sub-*
 12 *paragraph:*

13 “(T) *in the case of hospitals which furnish*
 14 *inpatient hospital services for which payment*
 15 *may be made under this title, to be a partici-*
 16 *parting provider of medical care—*

17 “(i) *under the contract health services*
 18 *program funded by the Indian Health Serv-*
 19 *ice and operated by the Indian Health*
 20 *Service, an Indian tribe, or tribal organiza-*
 21 *tion (as those terms are defined in section*
 22 *4 of the Indian Health Care Improvement*
 23 *Act), with respect to items and services that*
 24 *are covered under such program and fur-*
 25 *nished to an individual eligible for such*
 26 *items and services under such program; and*

1 “(ii) under a program funded by the
 2 Indian Health Service and operated by an
 3 urban Indian organization with respect to
 4 the purchase of items and services for an el-
 5 igible urban Indian (as those terms are de-
 6 fined in such section 4),
 7 in accordance with regulations promulgated by
 8 the Secretary regarding admission practices,
 9 payment methodology, and rates of payment (in-
 10 cluding the acceptance of no more than such
 11 payment rate as payment in full for such items
 12 and services).”.

13 (b) *EFFECTIVE DATE.*—The amendments made by this
 14 section shall apply as of a date specified by the Secretary
 15 of Health and Human Services (but in no case later than
 16 6 months after the date of enactment of this Act) to medi-
 17 care participation agreements in effect (or entered into) on
 18 or after such date.

19 **SEC. 413. GAO STUDY AND REPORT ON APPROPRIATENESS**
 20 **OF PAYMENTS UNDER THE PROSPECTIVE**
 21 **PAYMENT SYSTEM FOR INPATIENT HOSPITAL**
 22 **SERVICES.**

23 (a) *STUDY.*—The Comptroller General of the United
 24 States, using the most current data available, shall conduct
 25 a study to determine—

1 (1) *the appropriate level and distribution of pay-*
 2 *ments in relation to costs under the prospective pay-*
 3 *ment system under section 1886 of the Social Security*
 4 *Act (42 U.S.C. 1395ww) for inpatient hospital serv-*
 5 *ices furnished by subsection (d) hospitals (as defined*
 6 *in subsection (d)(1)(B) of such section); and*

7 (2) *whether there is a need to adjust such pay-*
 8 *ments under such system to reflect legitimate dif-*
 9 *ferences in costs across different geographic areas,*
 10 *kinds of hospitals, and types of cases.*

11 (b) *REPORT.*—*Not later than 24 months after the date*
 12 *of enactment of this Act, the Comptroller General of the*
 13 *United States shall submit to Congress a report on the study*
 14 *conducted under subsection (a) together with such rec-*
 15 *ommendations for legislative and administrative action as*
 16 *the Comptroller General determines appropriate.*

17 **SEC. 414. RURAL COMMUNITY HOSPITAL DEMONSTRATION**
 18 **PROGRAM.**

19 (a) *ESTABLISHMENT OF RURAL COMMUNITY HOS-*
 20 *PITAL (RCH) DEMONSTRATION PROGRAM.*—

21 (1) *IN GENERAL.*—*The Secretary shall establish*
 22 *a demonstration program to test the feasibility and*
 23 *advisability of the establishment of rural community*
 24 *hospitals that furnish rural community hospital serv-*
 25 *ices to medicare beneficiaries.*

1 (2) *DESIGNATION OF RCHS.*—

2 (A) *APPLICATION.*—*Each hospital that is*
3 *located in a demonstration area described in*
4 *subparagraph (C) that desires to participate in*
5 *the demonstration program under this section*
6 *shall submit an application to the Secretary at*
7 *such time, in such manner, and containing such*
8 *information as the Secretary may require.*

9 (B) *DESIGNATION.*—*The Secretary shall*
10 *designate any hospital that is located in a dem-*
11 *onstration area described in subparagraph (C),*
12 *submits an application in accordance with sub-*
13 *paragraph (A), and meets the other requirements*
14 *of this section as a rural community hospital for*
15 *purposes of the demonstration program.*

16 (C) *DEMONSTRATION AREAS.*—*There shall*
17 *be four demonstration areas within this pro-*
18 *gram. Two of these demonstration areas de-*
19 *scribed in this subparagraph shall include Kan-*
20 *sas and Nebraska.*

21 (3) *DURATION.*—*The Secretary shall conduct the*
22 *demonstration program under this section for a 5-*
23 *year period.*

24 (4) *IMPLEMENTATION.*—*The Secretary shall im-*
25 *plement the demonstration program not later than*

1 *January 1, 2005, but may not implement the pro-*
 2 *gram before October 1, 2004.*

3 **(b) PAYMENT.—**

4 **(1) INPATIENT HOSPITAL SERVICES.—***The*
 5 *amount of payment under the demonstration program*
 6 *for inpatient hospital services furnished in a rural*
 7 *community hospital, other than such services fur-*
 8 *nished in a psychiatric or rehabilitation unit of the*
 9 *hospital which is a distinct part, is, at the election*
 10 *of the hospital in the application referred to in sub-*
 11 *section (a)(2)(A)—*

12 *(A) the reasonable costs of providing such*
 13 *services, without regard to the amount of the cus-*
 14 *tomary or other charge; or*

15 *(B) the amount of payment provided for*
 16 *under the prospective payment system for inpa-*
 17 *tient hospital services under section 1886(d) of*
 18 *the Social Security Act (42 U.S.C. 1395ww(d)).*

19 **(2) OUTPATIENT SERVICES.—***The amount of*
 20 *payment under the demonstration program for out-*
 21 *patient services furnished in a rural community hos-*
 22 *pital is, at the election of the hospital in the applica-*
 23 *tion referred to in subsection (a)(2)(A)—*

24 *(A) the reasonable costs of providing such*
 25 *services, without regard to the amount of the cus-*

1 *tomary or other charge and any limitation*
 2 *under section 1861(v)(1)(U) of the Social Secu-*
 3 *rity Act (42 U.S.C. 1395x(v)(1)(U)); or*

4 *(B) the amount of payment provided for*
 5 *under the prospective payment system for cov-*
 6 *ered OPD services under section 1833(t) of the*
 7 *Social Security Act (42 U.S.C. 1395l(t)).*

8 *(3) HOME HEALTH SERVICES.—In determining*
 9 *payments under the demonstration program for home*
 10 *health services furnished by a qualified RCH-based*
 11 *home health agency (as defined in paragraph (2))—*

12 *(A) the agency may make a one-time elec-*
 13 *tion to waive application of the prospective pay-*
 14 *ment system established under section 1895 of*
 15 *the Social Security Act (42 U.S.C. 1395fff) to*
 16 *such services furnished by the agency; and*

17 *(B) in the case of such an election, payment*
 18 *shall be made on the basis of the reasonable costs*
 19 *incurred in furnishing such services as deter-*
 20 *mined under section 1861(v) of the Social Secu-*
 21 *rity Act (42 U.S.C. 1395x(v)), but without re-*
 22 *gard to the amount of the customary or other*
 23 *charges with respect to such services or the limi-*
 24 *tations established under paragraph (1)(L) of*
 25 *such section.*

1 (4) *CONSOLIDATED BILLING.*—*The Secretary*
 2 *shall permit consolidated billing under section*
 3 *1842(b)(6)(E) of the Social Security Act (42 U.S.C.*
 4 *1395u(b)(6)(E)).*

5 (5) *EXEMPTION FROM 30 PERCENT REDUCTION IN*
 6 *REIMBURSEMENT FOR BAD DEBT.*—*In determining*
 7 *the reasonable costs for rural community hospitals,*
 8 *section 1861(v)(1)(T) of the Social Security Act (42*
 9 *U.S.C. 1395x(v)(1)(T)) shall not apply.*

10 (6) *BENEFICIARY COST-SHARING FOR OUT-*
 11 *PATIENT SERVICES.*—*The amounts of beneficiary cost-*
 12 *sharing for outpatient services furnished in a rural*
 13 *community hospital under the demonstration pro-*
 14 *gram shall be as follows:*

15 (A) *For items and services that would have*
 16 *been paid under section 1833(t) of the Social Se-*
 17 *curity Act (42 U.S.C. 1395l(t)) if provided by a*
 18 *hospital, the amount of cost-sharing determined*
 19 *under paragraph (8) of such section.*

20 (B) *For items and services that would have*
 21 *been paid under section 1833(h) of such Act (42*
 22 *U.S.C. 1395l(h)) if furnished by a provider or*
 23 *supplier, no cost-sharing shall apply.*

24 (C) *For all other items and services, the*
 25 *amount of cost-sharing that would apply to the*

1 *item or service under the methodology that would*
 2 *be used to determine payment for such item or*
 3 *service if provided by a physician, provider, or*
 4 *supplier, as the case may be.*

5 (7) *RETURN ON EQUITY.—*

6 (A) *IN GENERAL.—Notwithstanding sub-*
 7 *paragraph (P)(i) and (S)(i) of section*
 8 *1861(v)(1) of the Social Security Act (42 U.S.C.*
 9 *1395x(v)(1)) and section 1886(g)(2) of such Act*
 10 *(42 U.S.C. 1395ww(g)(2)), in determining the*
 11 *reasonable costs of the services described in sub-*
 12 *clause (II) furnished by a rural community hos-*
 13 *pital for payment of a return on equity capital*
 14 *at a rate of return equal to 150 percent of the*
 15 *average specified in section 1861(v)(1)(P)(i) of*
 16 *such Act (42 U.S.C. 1395x(v)(1)(P)(i)).*

17 (B) *SERVICES DESCRIBED.—The services re-*
 18 *ferred to in subclause (I) are rural community*
 19 *hospital services.*

20 (C) *DISREGARD OF PROPRIETARY PROVIDER*
 21 *STATUS.—Payment under the demonstration*
 22 *program shall be made without regard to wheth-*
 23 *er a provider is a proprietary provider.*

24 (8) *REMOVING BARRIERS TO ESTABLISHMENT OF*
 25 *DISTINCT PART UNITS BY RCH FACILITIES.—Notwith-*

1 *standing section 1886(d)(1)(B) of the Social Security*
 2 *Act (42 U.S.C. 1395ww(d)(1)(B)), the Secretary shall*
 3 *permit rural community hospitals to establish dis-*
 4 *tinct part units for purposes of applying such section.*
 5 *(c) FUNDING.—*

6 *(1) IN GENERAL.—The Secretary shall provide*
 7 *for the transfer from the Federal Hospital Insurance*
 8 *Trust Fund under section 1817 of the Social Security*
 9 *Act (42 U.S.C. 1395i) and the Federal Supple-*
 10 *mentary Insurance Trust Fund established under sec-*
 11 *tion 1841 of such Act (42 U.S.C. 1395t), in such pro-*
 12 *portion as the Secretary determines to be appropriate,*
 13 *of such funds as are necessary for the costs of car-*
 14 *rying out the demonstration program under this sec-*
 15 *tion.*

16 *(2) BUDGET NEUTRALITY.—In conducting the*
 17 *demonstration program under this section, the Sec-*
 18 *retary shall ensure that the aggregate payments made*
 19 *by the Secretary do not exceed the amount which the*
 20 *Secretary would have paid if the demonstration pro-*
 21 *gram under this section was not implemented.*

22 *(d) WAIVER AUTHORITY.—The Secretary may waive*
 23 *such requirements of titles XI and XVIII of the Social Secu-*
 24 *rity Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be*

1 *necessary for the purpose of carrying out the demonstration*
 2 *program under this section.*

3 *(e) REPORT.—Not later than 6 months after the com-*
 4 *pletion of the demonstration program under this section,*
 5 *the Secretary shall submit to Congress a report on such pro-*
 6 *gram, together with recommendations for such legislation*
 7 *and administrative action as the Secretary determines to*
 8 *be appropriate.*

9 *(f) DEFINITIONS.—In this section:*

10 *(1) RURAL COMMUNITY HOSPITAL.—*

11 *(A) IN GENERAL.—The term “rural commu-*
 12 *nity hospital” means a hospital (as defined in*
 13 *section 1861(e) of the Social Security Act (42*
 14 *U.S.C. 1395x(e))) that—*

15 *(i) is located in a rural area (as de-*
 16 *fined in section 1886(d)(2)(D) of such Act*
 17 *(42 U.S.C. 1395ww(d)(2)(D))) or treated as*
 18 *being so located pursuant to section*
 19 *1886(d)(8)(E) of such Act (42 U.S.C.*
 20 *1395ww(d)(8)(E));*

21 *(ii) subject to subparagraph (B), has*
 22 *less than 51 acute care inpatient beds, as*
 23 *reported in its most recent cost report;*

24 *(iii) makes available 24-hour emer-*
 25 *gency care services;*

(iv) subject to subparagraph (C), has a provider agreement in effect with the Secretary and is open to the public as of January 1, 2003; and

(v) applies to the Secretary for such designation.

(B) *TREATMENT OF PSYCHIATRIC AND REHABILITATION UNITS.*—For purposes of paragraph (1)(B), beds in a psychiatric or rehabilitation unit of the hospital which is a distinct part of the hospital shall not be counted.

(C) *TYPES OF HOSPITALS THAT MAY PARTICIPATE.*—Subparagraph (1)(D) shall not be construed to prohibit any of the following from qualifying as a rural community hospital:

(i) A replacement facility (as defined by the Secretary in regulations in effect on January 1, 2003) with the same service area (as defined by the Secretary in regulations in effect on such date).

(ii) A facility obtaining a new provider number pursuant to a change of ownership.

(iii) A facility which has a binding written agreement with an outside, unre-

lated party for the construction, reconstruction, lease, rental, or financing of a building as of January 1, 2003.

(D) *INCLUSION OF CAHS.*—Nothing in this subsection shall be construed as prohibiting a critical access hospital from qualifying as a rural community hospital if the critical access hospital meets the conditions otherwise applicable to hospitals under section 1861(e) of the Social Security Act (42 U.S.C. 1395x(e)) and section 1866 of such Act (42 U.S.C. 1395cc).

(2) *QUALIFIED RCH-BASED HOME HEALTH AGENCY DEFINED.*—The term “qualified RCH-based home health agency” is a home health agency that is a provider-based entity (as defined in section 404 of the Medicare, Medicaid, and SCHIP Benefits Improvement and Protection Act of 2000 (Public Law 106–554; Appendix F, 114 Stat. 2763A–506)) of a rural community hospital that is located—

(A) in a county in which no main or branch office of another home health agency is located; or

(B) at least 35 miles from any main or branch office of another home health agency.

1 **SEC. 415. CRITICAL ACCESS HOSPITAL IMPROVEMENT DEM-**
 2 **ONSTRATION PROGRAM.**

3 (a) *ESTABLISHMENT OF CRITICAL ACCESS HOSPITAL*
 4 *DEMONSTRATION PROGRAM.*—

5 (1) *IN GENERAL.*—*The Secretary shall establish*
 6 *a demonstration program to test various methods to*
 7 *improve the critical access hospital program under*
 8 *section 1820 of the Social Security Act (42 U.S.C.*
 9 *1395i–4).*

10 (2) *CRITICAL ACCESS HOSPITAL IMPROVE-*
 11 *MENT.*—*In conducting the demonstration program*
 12 *under this section, the Secretary shall apply rules*
 13 *with respect to critical access hospitals participating*
 14 *in the program as follows:*

15 (A) *EXCLUSION OF CERTAIN BEDS FROM*
 16 *BED COUNT.*—*In determining the number of beds*
 17 *of a facility for purposes of applying the bed*
 18 *limitations referred to in subsections*
 19 *(c)(2)(B)(iii) and (f) of section 1820 of the So-*
 20 *cial Security Act (42 U.S.C. 1395i–4), the Sec-*
 21 *retary shall not take into account any bed of a*
 22 *distinct part psychiatric or rehabilitation unit*
 23 *(described in the matter following clause (v) of*
 24 *section 1886(d)(1)(B) of such Act (42 U.S.C.*
 25 *1395ww(d)(1)(B))) of the facility, except that the*
 26 *total number of beds that are not taken into ac-*

1 *count pursuant to this subparagraph with re-*
2 *spect to a facility shall not exceed 10.*

3 *(B) EXCLUSION FROM HOME HEALTH*
4 *PPS.—Notwithstanding section 1895 of the So-*
5 *cial Security Act (42 U.S.C. 1395fff), in deter-*
6 *mining payments under the demonstration pro-*
7 *gram for home health services furnished by a*
8 *home health agency that is owned and operated*
9 *by a critical access hospital participating in the*
10 *demonstration program—*

11 *(i) the agency may make an election to*
12 *waive application of the prospective pay-*
13 *ment system established under such section*
14 *to such services furnished by the agency;*
15 *and*

16 *(ii) in the case of such an election,*
17 *payment shall be made on the basis of the*
18 *reasonable costs incurred in furnishing such*
19 *services as determined under section*
20 *1861(v), but without regard to the amount*
21 *of the customary or other charges with re-*
22 *spect to such services or the limitations es-*
23 *tablished under paragraph (1)(L) of such*
24 *section.*

1 (C) *EXEMPTION OF CAH FACILITIES FROM*
 2 *PPS.—Notwithstanding section 1888(e) of the So-*
 3 *cial Security Act (42 U.S.C. 1395yy(e)), in de-*
 4 *termining payments under this part for covered*
 5 *skilled nursing facility services furnished by a*
 6 *skilled nursing facility that is a distinct part*
 7 *unit of a critical access hospital participating in*
 8 *the demonstration program or is owned and op-*
 9 *erated by a critical access hospital participating*
 10 *in the demonstration program—*

11 (i) *the prospective payment system es-*
 12 *tablished under such section shall not apply;*
 13 *and*

14 (ii) *payment shall be made on the*
 15 *basis of the reasonable costs incurred in fur-*
 16 *nishing such services as determined under*
 17 *section 1861(v) of such Act (42 U.S.C.*
 18 *1395x(v)), but without regard to the amount*
 19 *of the customary or other charges with re-*
 20 *spect to such services.*

21 (D) *CONSOLIDATED BILLING.—The Sec-*
 22 *retary shall permit consolidated billing under*
 23 *section 1842(b)(6)(E) of the Social Security Act*
 24 *(42 U.S.C. 1395u(b)(6)(E)).*

1 (E) *EXEMPTION OF CERTAIN DISTINCT PART*
 2 *PSYCHIATRIC OR REHABILITATION UNITS FROM*
 3 *COST LIMITS.*—*Notwithstanding section 1886(b)*
 4 *of the Social Security Act (42 U.S.C.*
 5 *1395ww(b)), in determining payments under the*
 6 *demonstration program for inpatient hospital*
 7 *services furnished by a distinct part psychiatric*
 8 *or rehabilitation unit (described in the matter*
 9 *following section 1886(d)(1)(B)(v) of such Act*
 10 *(42 U.S.C. 1395ww(d)(1)(B)(v))) of a critical*
 11 *access hospital participating in the demonstra-*
 12 *tion program—*

13 (i) *the limits imposed under the pre-*
 14 *ceding paragraphs of this subsection shall*
 15 *not apply; and*

16 (ii) *payment shall be made on the*
 17 *basis of the reasonable costs incurred in fur-*
 18 *nishing such services as determined under*
 19 *section 1861(v) of such Act (42 U.S.C.*
 20 *1395x(v)), but without regard to the amount*
 21 *of the customary or other charges with re-*
 22 *spect to such services.*

23 (F) *RETURN ON EQUITY.*—

24 (i) *IN GENERAL.*—*Notwithstanding*
 25 *subparagraph (P)(i) and (S)(i) of section*

1 1861(v)(1) of the Social Security Act (42
 2 U.S.C. 1395x(v)(1)) and section 1886(g)(2)
 3 of such Act (42 U.S.C. 1395ww(g)(2)), in
 4 determining the reasonable costs of the serv-
 5 ices described in subclause (II) furnished by
 6 a critical access hospital participating in
 7 the demonstration program for payment of
 8 a return on equity capital at a rate of re-
 9 turn equal to 150 percent of the average
 10 specified in section 1861(v)(1)(P)(i) of such
 11 Act (42 U.S.C. 1395x(v)(1)(P)(i)).

12 (ii) *SERVICES DESCRIBED.*—The serv-
 13 ices referred to in subclause (I) are inpa-
 14 tient critical access hospital services, out-
 15 patient critical access hospital services, ex-
 16 tended care services, posthospital extended
 17 care services, home health services, ambu-
 18 lance services, and inpatient hospital serv-
 19 ices.

20 (iii) *DISREGARD OF PROPRIETARY*
 21 *PROVIDER STATUS.*—Payment under the
 22 demonstration program shall be made with-
 23 out regard to whether a provider is a pro-
 24 prietary provider.

1 (G) *REMOVING BARRIERS TO ESTABLISH-*
 2 *MENT OF DISTINCT PART UNITS BY CAH FACILI-*
 3 *TIES.*—*Notwithstanding section 1886(d)(1)(B) of*
 4 *the Social Security Act (42 U.S.C.*
 5 *1395ww(d)(1)(B)), the Secretary shall permit*
 6 *critical access hospitals participating in the*
 7 *demonstration program to establish distinct part*
 8 *units for purposes of applying such section.*

9 (3) *PARTICIPATION OF CAHS.*—

10 (A) *APPLICATION.*—*Each critical access*
 11 *hospital that is located in a demonstration area*
 12 *described in subparagraph (C) that desires to*
 13 *participate in the demonstration program under*
 14 *this section shall submit an application to the*
 15 *Secretary at such time, in such manner, and*
 16 *containing such information as the Secretary*
 17 *may require.*

18 (B) *PARTICIPATION.*—*The Secretary shall*
 19 *permit any critical access hospital that is located*
 20 *in a demonstration area described in subpara-*
 21 *graph (C), submits an application in accordance*
 22 *with subparagraph (A), and meets the other re-*
 23 *quirements of this section to participate in the*
 24 *demonstration program.*

1 (C) *DEMONSTRATION AREAS.*—*There shall*
 2 *be four demonstration areas within this pro-*
 3 *gram. Two of these demonstration areas de-*
 4 *scribed in this subparagraph shall include Kan-*
 5 *sas and Nebraska.*

6 (4) *DURATION.*—*The Secretary shall conduct the*
 7 *demonstration program under this section for a 5-*
 8 *year period.*

9 (5) *IMPLEMENTATION.*—*The Secretary shall im-*
 10 *plement the demonstration program not later than*
 11 *January 1, 2005, but may not implement the pro-*
 12 *gram before October 1, 2004.*

13 (b) *FUNDING.*—

14 (1) *IN GENERAL.*—*The Secretary shall provide*
 15 *for the transfer from the Federal Hospital Insurance*
 16 *Trust Fund under section 1817 of the Social Security*
 17 *Act (42 U.S.C. 1395i) and the Federal Supple-*
 18 *mentary Insurance Trust Fund established under sec-*
 19 *tion 1841 of such Act (42 U.S.C. 1395t), in such pro-*
 20 *portion as the Secretary determines to be appropriate,*
 21 *of such funds as are necessary for the costs of car-*
 22 *rying out the demonstration program under this sec-*
 23 *tion.*

24 (2) *BUDGET NEUTRALITY.*—*In conducting the*
 25 *demonstration program under this section, the Sec-*

1 *retary shall ensure that the aggregate payments made*
 2 *by the Secretary do not exceed the amount which the*
 3 *Secretary would have paid if the demonstration pro-*
 4 *gram under this section was not implemented.*

5 *(c) WAIVER AUTHORITY.—The Secretary may waive*
 6 *such requirements of titles XI and XVIII of the Social Secu-*
 7 *rity Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be*
 8 *necessary for the purpose of carrying out the demonstration*
 9 *program under this section.*

10 *(d) REPORT.—Not later than 6 months after the com-*
 11 *pletion of the demonstration program under this section,*
 12 *the Secretary shall submit to Congress a report on such pro-*
 13 *gram, together with recommendations for such legislation*
 14 *and administrative action as the Secretary determines to*
 15 *be appropriate.*

16 **SEC. 416. TREATMENT OF GRANDFATHERED LONG-TERM**
 17 **CARE HOSPITALS.**

18 *(a) IN GENERAL.—The last sentence of section*
 19 *1886(d)(1)(B) is amended by inserting “, and the Secretary*
 20 *may not impose any special conditions on the operation,*
 21 *size, number of beds, or location of any hospital so classified*
 22 *for continued participation under this title or title XIX or*
 23 *for continued classification as a hospital described in clause*
 24 *(iv)” before the period at the end.*

1 (b) *TREATMENT OF PROPOSED REVISION.*—The Sec-
 2 retary shall not adopt the proposed revision to section
 3 412.22(f) of title 42, Code of Federal Regulations contained
 4 in 68 Federal Register 27154 (May 19, 2003) or any revi-
 5 sion reaching the same or substantially the same result as
 6 such revision.

7 (c) *EFFECTIVE DATE.*—The amendment made by, and
 8 provisions of, this section shall apply to cost reporting peri-
 9 ods ending on or after December 31, 2002.

10 **SEC. 417. TREATMENT OF CERTAIN ENTITIES FOR PUR-**
 11 **POSES OF PAYMENTS UNDER THE MEDICARE**
 12 **PROGRAM.**

13 (a) *PAYMENTS TO HOSPITALS.*—

14 (1) *IN GENERAL.*—Notwithstanding any other
 15 provision of law, effective for discharges occurring on
 16 or after October 1, 2003, for purposes of making pay-
 17 ments to hospitals (as defined in section 1886(d) and
 18 1833(t) of the Social Security Act (42 U.S.C.
 19 1395(d)) under the medicare program under title
 20 XVIII of such Act (42 U.S.C. 1395 et seq.), Iredell
 21 County, North Carolina, and Rowan County, North
 22 Carolina, are deemed to be located in the Charlotte-
 23 Gastonia-Rock Hill, North Carolina, South Carolina
 24 Metropolitan Statistical Area.

1 (2) *BUDGET NEUTRAL WITHIN NORTH CARO-*
 2 *LINA.—The Secretary shall adjust the area wage*
 3 *index referred to in paragraph (1) with respect to*
 4 *payments to hospitals located in North Carolina in a*
 5 *manner which assures that the total payments made*
 6 *under section 1886(d) of the Social Security Act (42*
 7 *U.S.C., 1395(w)(d)) in a fiscal year for the oper-*
 8 *ating cost of inpatient hospital services are not great-*
 9 *er or less than the total of such payments that would*
 10 *have been made in the year if this subsection had not*
 11 *been enacted.*

12 (b) *PAYMENTS TO SKILLED NURSING FACILITIES AND*
 13 *HOME HEALTH AGENCIES.—*

14 (1) *IN GENERAL.—Notwithstanding any other*
 15 *provision of law, effective beginning October 1, 2003,*
 16 *for purposes of making payments to skilled nursing*
 17 *facilities (SNFs) and home health agencies (as defined*
 18 *in sections 1861(j) and 1861(o) of the Social Security*
 19 *Act (42 U.S.C. 1395x(j); 1395x(o)) under the medi-*
 20 *care program under title XVIII of such Act, Iredell*
 21 *County, North Carolina, and Rowan County, North*
 22 *Carolina, are deemed to be located in the Charlotte-*
 23 *Gastonia-Rock Hill, North Carolina, South Carolina*
 24 *Metropolitan Statistical Area.*

1 (2) *APPLICATION AND BUDGET NEUTRAL WITHIN*
2 *NORTH CAROLINA.—Effective for fiscal year 2004, the*
3 *skilled nursing facility PPS and home health PPS*
4 *rates for Iredell County, North Carolina, and Rowan*
5 *County, North Carolina, will be updated by the*
6 *prefloor, prereclassified hospital wage index available*
7 *for the Charlotte-Gastonia-Rock Hill, North Carolina,*
8 *South Carolina Metropolitan Statistical Area. This*
9 *subsection shall be implemented in a budget neutral*
10 *manner, using a methodology that ensures that the*
11 *total amount of expenditures for skilled nursing facil-*
12 *ity services and home health services in a year does*
13 *not exceed the total amount of expenditures that*
14 *would have been made in the year if this subsection*
15 *had not been enacted. Required adjustments by reason*
16 *of the preceding sentence shall be done with respect to*
17 *skilled nursing facilities and home health agencies lo-*
18 *cated in North Carolina.*

19 (c) *CONSTRUCTION.—The provisions of this section*
20 *shall have no effect on the amount of payments made under*
21 *title XVIII of the Social Security Act to entities located in*
22 *States other than North Carolina.*

1 **SEC. 418. REVISION OF THE INDIRECT MEDICAL EDU-**
 2 **CATION (IME) ADJUSTMENT PERCENTAGE.**

3 (a) *IN GENERAL.*—Section 1886(d)(5)(B)(ii) (42
 4 U.S.C. 1395ww(d)(5)(B)(ii)) is amended—

5 (1) in subclause (VI), by striking “and” after the
 6 semicolon at the end;

7 (2) in subclause (VII)—

8 (A) by striking “on or after October 1,
 9 2002” and inserting “during fiscal year 2003”;
 10 and

11 (B) by striking the period at the end and
 12 inserting a semicolon; and

13 (3) by adding at the end the following new sub-
 14 clauses:

15 “(VIII) during each of fiscal years 2004
 16 and 2005, ‘c’ is equal to 1.36; and

17 “(IX) on or after October 1, 2005, ‘c’ is
 18 equal to 1.355.”.

19 (b) *CONFORMING AMENDMENT RELATING TO DETER-*
 20 *MINATION OF STANDARDIZED AMOUNT.*—Section
 21 1886(d)(2)(C)(i) (42 U.S.C. 1395ww(d)(2)(C)(i)) is
 22 amended—

23 (1) by striking “1999 or” and inserting “1999,”;
 24 and

25 (2) by inserting “, or the Prescription Drug and
 26 Medicare Improvement Act of 2003” after “2000”.

1 (c) *EFFECTIVE DATE.*—*The amendments made by this*
 2 *section shall apply to discharges occurring on or after Octo-*
 3 *ber 1, 2003.*

4 **SEC. 419. CALCULATION OF WAGE INDICES FOR HOSPITALS.**

5 *Notwithstanding any other provision of law, in the*
 6 *calculation of a wage index in a State for purposes of mak-*
 7 *ing payments for discharges occurring during fiscal year*
 8 *2004, the Secretary may waive such other criteria for re-*
 9 *classification, as deemed appropriate by the Secretary.*

10 **SEC. 420. CONFORMING CHANGES REGARDING FEDERALLY**
 11 **QUALIFIED HEALTH CENTERS.**

12 *Section 1833(a)(3) (42 U.S.C. 1395l(a)(3)) is amended*
 13 *by inserting “(which regulations shall exclude any cost in-*
 14 *curred for the provision of services pursuant to a contract*
 15 *with an eligible entity (as defined in section 1860D(4)) op-*
 16 *erating a Medicare Prescription Drug plan or with an enti-*
 17 *ty with a contract under section 1860D–13(e), for which*
 18 *payment is made by the entity)” after “the Secretary may*
 19 *prescribe in regulations”.*

20 **SEC. 420A. INCREASE FOR HOSPITALS WITH DISPROPOR-**
 21 **TIONATE INDIGENT CARE REVENUES.**

22 (a) *DISPROPORTIONATE SHARE ADJUSTMENT PER-*
 23 *CENTAGE.*—*Section 1886(d)(5)(F)(iii) (42 U.S.C.*
 24 *1395ww(d)(5)(F)(iii)) is amended by striking “35 percent”*

1 *and inserting “35 percent (or, for discharges occurring on*
 2 *or after October 1, 2003, 40 percent)”.*

3 (b) *CAPITAL COSTS.—Section 1886(g)(1)(B) (42*
 4 *U.S.C. 1395ww(g)(1)(B)) is amended—*

5 (1) *in clause (iii), by striking “and” at the end;*

6 (2) *in clause (iv), by striking the period at the*
 7 *end and inserting “, and”; and*

8 (3) *by adding at the end the following new*
 9 *clause:*

10 “(v) *in the case of cost reporting periods begin-*
 11 *ning on or after October 1, 2003, shall provide for a*
 12 *disproportionate share adjustment in the same man-*
 13 *ner as section 1886(d)(5)(F)(iii).”.*

14 **SEC. 420B. TREATMENT OF GRANDFATHERED LONG-TERM**
 15 **CARE HOSPITALS.**

16 (a) *IN GENERAL.—The last sentence of section*
 17 *1886(d)(1)(B) is amended by inserting “, and the Secretary*
 18 *may not impose any special conditions on the operation,*
 19 *size, number of beds, or location of any hospital so classified*
 20 *for continued participation under this title or title XIX or*
 21 *for continued classification as a hospital described in clause*
 22 *(iv)” before the period at the end.*

23 (b) *TREATMENT OF PROPOSED REVISION.—The Sec-*
 24 *retary shall not adopt the proposed revision to section*
 25 *412.22(f) of title 42, Code of Federal Regulations contained*

1 in 68 *Federal Register* 27154 (May 19, 2003) or any revision reaching the same or substantially the same result as
 2 such revision.

4 (c) *EFFECTIVE DATE.*—The amendment made by, and
 5 provisions of, this section shall apply to cost reporting periods ending on or after December 31, 2002.

7 ***Subtitle B—Provisions Relating to*** 8 ***Part B***

9 ***SEC. 421. ESTABLISHMENT OF FLOOR ON GEOGRAPHIC AD-*** 10 ***JUSTMENTS OF PAYMENTS FOR PHYSICIANS’*** 11 ***SERVICES.***

12 Section 1848(e)(1) (42 U.S.C. 1395w–4(e)(1)) is
 13 amended—

14 (1) in subparagraph (A), by striking “subpara-
 15 graphs (B) and (C)” and inserting “subparagraphs
 16 (B), (C), (E), and (F)”; and

17 (2) by adding at the end the following new sub-
 18 paragraphs:

19 “(E) *FLOOR FOR WORK GEOGRAPHIC INDICES.*—
 20

21 “(i) *IN GENERAL.*—For purposes of
 22 payment for services furnished on or after
 23 January 1, 2004, and before January 1,
 24 2008, after calculating the work geographic
 25 indices in subparagraph (A)(iii), the Sec-

retary shall increase the work geographic index to the work floor index for any locality for which such geographic index is less than the work floor index.

“(ii) WORK FLOOR INDEX.—For purposes of clause (i), the term ‘applicable floor index’ means—

“(I) 0.980 with respect to services furnished during 2004; and

“(II) 1.000 for services furnished during 2005, 2006, and 2007.

“(F) FLOOR FOR PRACTICE EXPENSE AND MALPRACTICE GEOGRAPHIC INDICES.—For purposes of payment for services furnished on or after January 1, 2005, and before January 1, 2008, after calculating the practice expense and malpractice indices in clauses (i) and (ii) of subparagraph (A) and in subparagraph (B), the Secretary shall increase any such index to 1.00 for any locality for which such index is less than 1.00.”.

SEC. 422. MEDICARE INCENTIVE PAYMENT PROGRAM IMPROVEMENTS.

(a) PROCEDURES FOR SECRETARY, AND NOT PHYSICIANS, TO DETERMINE WHEN BONUS PAYMENTS UNDER

1 *MEDICARE INCENTIVE PAYMENT PROGRAM SHOULD BE*
 2 *MADE.*—Section 1833(m) (42 U.S.C. 1395l(m)) is
 3 *amended—*

4 (1) *by inserting “(1)” after “(m)”;* and

5 (2) *by adding at the end the following new para-*
 6 *graph:*

7 “(2) *The Secretary shall establish procedures under*
 8 *which the Secretary, and not the physician furnishing the*
 9 *service, is responsible for determining when a payment is*
 10 *required to be made under paragraph (1).”.*

11 (b) *EDUCATIONAL PROGRAM REGARDING THE MEDI-*
 12 *CARE INCENTIVE PAYMENT PROGRAM.*—*The Secretary shall*
 13 *establish and implement an ongoing educational program*
 14 *to provide education to physicians under the medicare pro-*
 15 *gram on the medicare incentive payment program under*
 16 *section 1833(m) of the Social Security Act (42 U.S.C.*
 17 *1395l(m)).*

18 (c) *ONGOING GAO STUDY AND ANNUAL REPORT ON*
 19 *THE MEDICARE INCENTIVE PAYMENT PROGRAM.*—

20 (1) *ONGOING STUDY.*—*The Comptroller General*
 21 *of the United States shall conduct an ongoing study*
 22 *on the medicare incentive payment program under*
 23 *section 1833(m) of the Social Security Act (42 U.S.C.*
 24 *1395l(m)). Such study shall focus on whether such*
 25 *program increases the access of medicare beneficiaries*

1 *who reside in an area that is designated (under sec-*
 2 *tion 332(a)(1)(A) of the Public Health Service Act*
 3 *(42 U.S.C. 254e(a)(1)(A))) as a health professional*
 4 *shortage area to physicians' services under the medi-*
 5 *care program.*

6 (2) *ANNUAL REPORTS.*—*Not later than 1 year*
 7 *after the date of enactment of this Act, and annually*
 8 *thereafter, the Comptroller General of the United*
 9 *States shall submit to Congress a report on the study*
 10 *conducted under paragraph (1), together with rec-*
 11 *ommendations as the Comptroller General considers*
 12 *appropriate.*

13 **SEC. 423. EXTENSION OF HOLD HARMLESS PROVISIONS**
 14 **FOR SMALL RURAL HOSPITALS AND TREAT-**
 15 **MENT OF CERTAIN SOLE COMMUNITY HOS-**
 16 **PITALS TO LIMIT DECLINE IN PAYMENT**
 17 **UNDER THE OPD PPS.**

18 (a) *SMALL RURAL HOSPITALS.*—*Section*
 19 *1833(t)(7)(D)(i) (42 U.S.C. 1395l(t)(7)(D)(i)) is amended*
 20 *by inserting “and during 2006” after “2004,”.*

21 (b) *SOLE COMMUNITY HOSPITALS.*—*Section*
 22 *1833(t)(7)(D) (42 U.S.C. 1395l(t)(7)(D)) is amended by*
 23 *adding at the end the following:*

24 *“(iii) TEMPORARY TREATMENT FOR*
 25 *SOLE COMMUNITY HOSPITALS.—In the case*

1 of a sole community hospital (as defined in
 2 section 1886(d)(5)(D)(iii)) located in a
 3 rural area, for covered OPD services fur-
 4 nished in 2006, for which the PPS amount
 5 is less than the pre-BBA amount, the
 6 amount of payment under this subsection
 7 shall be increased by the amount of such
 8 difference.”.

9 **SEC. 424. INCREASE IN PAYMENTS FOR CERTAIN SERVICES**
 10 **FURNISHED BY SMALL RURAL AND SOLE**
 11 **COMMUNITY HOSPITALS UNDER MEDICARE**
 12 **PROSPECTIVE PAYMENT SYSTEM FOR HOS-**
 13 **PITAL OUTPATIENT DEPARTMENT SERVICES.**

14 (a) *INCREASE.*—

15 (1) *IN GENERAL.*—In the case of an applicable
 16 covered OPD service (as defined in paragraph (2))
 17 that is furnished by a hospital described in clause (i)
 18 or (iii) of paragraph (7)(D) of section 1833(t) of the
 19 Social Security Act (42 U.S.C. 1395l(t)), as amended
 20 by section 424, on or after January 1, 2005, and be-
 21 fore January 1, 2008, the Secretary shall increase the
 22 medicare OPD fee schedule amount (as determined
 23 under paragraph (4)(A) of such section) that is appli-
 24 cable for such service in that year (determined with-

1 out regard to any increase under this section in a
 2 previous year) by 5 percent.

3 (2) *APPLICABLE COVERED OPD SERVICES DE-*
 4 *FINED.*—For purposes of this section, the term “appli-
 5 cable covered OPD service” means a covered clinic or
 6 emergency room visit that is classified within the
 7 groups of covered OPD services (as defined in para-
 8 graph (1)(B) of section 1833(t) of the Social Security
 9 Act (42 U.S.C. 1395l(t))) established under paragraph
 10 (2)(B) of such section.

11 (b) *NO EFFECT ON COPAYMENT AMOUNT.*—The Sec-
 12 retary shall compute the copayment amount for applicable
 13 covered OPD services under section 1833(t)(8)(A) of the So-
 14 cial Security Act (42 U.S.C. 1395l(t)(8)(A)) as if this sec-
 15 tion had not been enacted.

16 (c) *NO EFFECT ON INCREASE UNDER HOLD HARM-*
 17 *LESS OR OUTLIER PROVISIONS.*—The Secretary shall apply
 18 the temporary hold harmless provision under clause (i) and
 19 (iii) of paragraph (7)(D) of section 1833(t) of the Social
 20 Security Act (42 U.S.C. 1395l(t)) and the outlier provision
 21 under paragraph (5) of such section as if this section had
 22 not been enacted.

23 (d) *WAIVING BUDGET NEUTRALITY AND NO REVISION*
 24 *OR ADJUSTMENTS.*—The Secretary shall not make any revi-
 25 sion or adjustment under subparagraph (A), (B), or (C)

1 of section 1833(t)(9) of the Social Security Act (42 U.S.C.
2 1395l(t)(9)) because of the application of subsection (a)(1).

3 (e) *NO EFFECT ON PAYMENTS AFTER INCREASE PE-*
4 *RIOD ENDS.*—*The Secretary shall not take into account any*
5 *payment increase provided under subsection (a)(1) in deter-*
6 *mining payments for covered OPD services (as defined in*
7 *paragraph (1)(B) of section 1833(t) of the Social Security*
8 *Act (42 U.S.C. 1395l(t))) under such section that are fur-*
9 *nished after January 1, 2008.*

10 (f) *TECHNICAL AMENDMENT.*—*Section 1833(t)(2)(B)*
11 *(42 U.S.C. 1395l(t)(2)(B)) is amended by inserting “(and*
12 *periodically revise such groups pursuant to paragraph*
13 *(9)(A))” after “establish groups”.*

14 **SEC. 425. TEMPORARY INCREASE FOR GROUND AMBU-**
15 **LANCE SERVICES.**

16 *Section 1834(l) (42 U.S.C. 1395m(l)), as amended by*
17 *section 405(b)(2), is amended by adding at the end the fol-*
18 *lowing new paragraphs:*

19 “(10) *TEMPORARY INCREASE FOR GROUND AM-*
20 *BULANCE SERVICES.*—

21 “(A) *IN GENERAL.*—*Notwithstanding any*
22 *other provision of this subsection, in the case of*
23 *ground ambulance services furnished on or after*
24 *January 1, 2005, and before January 1, 2008,*
25 *for which the transportation originates in—*

1 “(i) a rural area described in para-
 2 graph (9) or in a rural census tract de-
 3 scribed in such paragraph, the fee schedule
 4 established under this section shall provide
 5 that the rate for the service otherwise estab-
 6 lished, after application of any increase
 7 under such paragraph, shall be increased by
 8 5 percent; and

9 “(ii) an area not described in clause
 10 (i), the fee schedule established under this
 11 section shall provide that the rate for the
 12 service otherwise established shall be in-
 13 creased by 2 percent.

14 “(B) APPLICATION OF INCREASED PAY-
 15 MENTS AFTER 2007.—The increased payments
 16 under subparagraph (A) shall not be taken into
 17 account in calculating payments for services fur-
 18 nished on or after the period specified in such
 19 subparagraph.

20 “(11) CONVERSION FACTOR ADJUSTMENTS.—The
 21 Secretary shall not adjust downward the conversion
 22 factor in any year because of an evaluation of the
 23 prior year conversion factor.”.

1 **SEC. 426. ENSURING APPROPRIATE COVERAGE OF AIR AM-**
 2 **BULANCE SERVICES UNDER AMBULANCE FEE**
 3 **SCHEDULE.**

4 (a) *COVERAGE.*—Section 1834(l) (42 U.S.C.
 5 1395m(l)), as amended by section 426, is amended by add-
 6 ing at the end the following new paragraph:

7 “(11) *ENSURING APPROPRIATE COVERAGE OF*
 8 *AIR AMBULANCE SERVICES.*—

9 “(A) *IN GENERAL.*—The regulations de-
 10 scribed in section 1861(s)(7) shall ensure that
 11 air ambulance services (as defined in subpara-
 12 graph (C)) are reimbursed under this subsection
 13 at the air ambulance rate if the air ambulance
 14 service—

15 “(i) is medically necessary based on
 16 the health condition of the individual being
 17 transported at or immediately prior to the
 18 time of the transport; and

19 “(ii) complies with equipment and
 20 crew requirements established by the Sec-
 21 retary.

22 “(B) *MEDICALLY NECESSARY.*—An air am-
 23 bulance service shall be considered to be medi-
 24 cally necessary for purposes of subparagraph
 25 (A)(i) if such service is requested—

1 “(i) by a physician or a hospital in
2 accordance with the physician’s or hos-
3 pital’s responsibilities under section 1867
4 (commonly known as the Emergency Med-
5 ical Treatment and Active Labor Act);

6 “(ii) as a result of a protocol estab-
7 lished by a State or regional emergency
8 medical service (EMS) agency;

9 “(iii) by a physician, nurse practi-
10 tioner, physician assistant, registered nurse,
11 or emergency medical responder who rea-
12 sonably determines or certifies that the pa-
13 tient’s condition is such that the time need-
14 ed to transport the individual by land or
15 the lack of an appropriate ground ambu-
16 lance, significantly increases the medical
17 risks for the individual; or

18 “(iv) by a Federal or State agency to
19 relocate patients following a natural dis-
20 aster, an act of war, or a terrorist attack.

21 “(C) AIR AMBULANCE SERVICES DE-
22 FINED.—For purposes of this paragraph, the
23 term ‘air ambulance service’ means fixed wing
24 and rotary wing air ambulance services.”.

1 (b) *CONFORMING AMENDMENT.*—Section 1861(s)(7)
 2 (42 U.S.C. 1395x(s)(7)) is amended by inserting “, subject
 3 to section 1834(l)(11),” after “but”.

4 (c) *EFFECTIVE DATE.*—The amendments made by this
 5 section shall apply to services furnished on or after January
 6 1, 2005.

7 **SEC. 427. TREATMENT OF CERTAIN CLINICAL DIAGNOSTIC**
 8 **LABORATORY TESTS FURNISHED BY A SOLE**
 9 **COMMUNITY HOSPITAL.**

10 Notwithstanding subsections (a), (b), and (h) of section
 11 1833 of the Social Security Act (42 U.S.C. 1395l) and sec-
 12 tion 1834(d)(1) of such Act (42 U.S.C. 1395m(d)(1)), in
 13 the case of a clinical diagnostic laboratory test covered
 14 under part B of title XVIII of such Act that is furnished
 15 in 2005 or 2006 by a sole community hospital (as defined
 16 in section 1886(d)(5)(D)(iii) of such Act (42 U.S.C.
 17 1395ww(d)(5)(D)(iii))) as part of services furnished to pa-
 18 tients of the hospital, the following rules shall apply:

19 (1) *PAYMENT BASED ON REASONABLE COSTS.*—
 20 The amount of payment for such test shall be 100 per-
 21 cent of the reasonable costs of the hospital in fur-
 22 nishing such test.

23 (2) *NO BENEFICIARY COST-SHARING.*—Notwith-
 24 standing section 432, no coinsurance, deductible, co-
 25 payment, or other cost-sharing otherwise applicable

1 *under such part B shall apply with respect to such*
 2 *test.*

3 **SEC. 428. IMPROVEMENT IN RURAL HEALTH CLINIC REIM-**
 4 **BURSEMENT.**

5 *Section 1833(f) (42 U.S.C. 1395l(f)) is amended—*

6 *(1) in paragraph (1), by striking “, and” at the*
 7 *end and inserting a semicolon;*

8 *(2) in paragraph (2)—*

9 *(A) by striking “in a subsequent year” and*
 10 *inserting “in 1989 through 2004”; and*

11 *(B) by striking the period at the end and*
 12 *inserting a semicolon; and*

13 *(3) by adding at the end the following new para-*
 14 *graphs:*

15 *“(3) in 2005, at \$80 per visit; and*

16 *“(4) in a subsequent year, at the limit estab-*
 17 *lished under this subsection for the previous year in-*
 18 *creased by the percentage increase in the MEI (as so*
 19 *defined) applicable to primary care services (as so de-*
 20 *finied) furnished as of the first day of that year.”.*

1 **SEC. 429. ELIMINATION OF CONSOLIDATED BILLING FOR**
 2 **CERTAIN SERVICES UNDER THE MEDICARE**
 3 **PPS FOR SKILLED NURSING FACILITY SERV-**
 4 **ICES.**

5 *(a) CERTAIN RURAL HEALTH CLINIC AND FEDERALLY*
 6 *QUALIFIED HEALTH CENTER SERVICES.—Section 1888(e)*
 7 *(42 U.S.C. 1395yy(e)) is amended—*

8 *(1) in paragraph (2)(A)(i)(II), by striking*
 9 *“clauses (ii) and (iii)” and inserting “clauses (ii),*
 10 *(iii), and (iv)”;* and

11 *(2) by adding at the end of paragraph (2)(A) the*
 12 *following new clause:*

13 *“(iv) EXCLUSION OF CERTAIN RURAL*
 14 *HEALTH CLINIC AND FEDERALLY QUALIFIED*
 15 *HEALTH CENTER SERVICES.—Services de-*
 16 *scribed in this clause are—*

17 *“(I) rural health clinic services*
 18 *(as defined in paragraph (1) of section*
 19 *1861(aa)); and*

20 *“(II) Federally qualified health*
 21 *center services (as defined in para-*
 22 *graph (3) of such section);*

23 *that would be described in clause (ii) if such*
 24 *services were furnished by a physician or*
 25 *practitioner not affiliated with a rural*

1 *health clinic or a Federally qualified health*
 2 *center.”.*

3 (b) *CERTAIN SERVICES FURNISHED BY AN ENTITY*
 4 *JOINTLY OWNED BY HOSPITALS AND CRITICAL ACCESS*
 5 *HOSPITALS.—For purposes of applying section 411.15(p)–*
 6 *(3)(iii) of title 42 of the Code of Federal Regulations, the*
 7 *Secretary shall treat an entity that is 100 percent owned*
 8 *as a joint venture by 2 Medicare-participating hospitals or*
 9 *critical access hospitals as a Medicare-participating hos-*
 10 *pital or a critical access hospital.*

11 (c) *TECHNICAL AMENDMENTS.—Sections*
 12 *1842(b)(6)(E) and 1866(a)(1)(H)(ii) (42 U.S.C.*
 13 *1395u(b)(6)(E); 1395cc(a)(1)(H)(ii)) are each amended by*
 14 *striking “section 1888(e)(2)(A)(ii)” and inserting “clauses*
 15 *(ii), (iii), and (iv) of section 1888(e)(2)(A)”.*

16 (d) *EFFECTIVE DATE.—The amendments made by this*
 17 *section and the provision of subsection (b) shall apply to*
 18 *services furnished on or after January 1, 2005.*

19 **SEC. 430. FREEZE IN PAYMENTS FOR CERTAIN ITEMS OF**
 20 **DURABLE MEDICAL EQUIPMENT AND CER-**
 21 **TAIN ORTHOTICS; ESTABLISHMENT OF QUAL-**
 22 **ITY STANDARDS AND ACCREDITATION RE-**
 23 **QUIREMENTS FOR DME PROVIDERS.**

24 (a) *FREEZE FOR DME.—Section 1834(a)(14) (42*
 25 *U.S.C. 1395m(a)(14)) is amended—*

1 (1) in subparagraph (E), by striking “and” at
2 the end;

3 (2) in subparagraph (F)—

4 (A) by striking “a subsequent year” and in-
5 serting “2003”; and

6 (B) by striking “the previous year.” and in-
7 serting “2002;”; and

8 (3) by adding at the end the following new sub-
9 paragraphs:

10 “(G) for each of the years 2004 through
11 2010—

12 “(i) in the case of class III medical de-
13 vices described in section 513(a)(1)(C) of
14 the Federal Food, Drug, and Cosmetic Act
15 (21 U.S.C. 360(c)(1)(C)), the percentage in-
16 crease described in subparagraph (B) for
17 the year involved; and

18 “(ii) in the case of covered items not
19 described in clause (i), 0 percentage points;
20 and

21 “(H) for a subsequent year, the percentage
22 increase described in subparagraph (B) for the
23 year involved.”.

1 (b) *FREEZE FOR OFF-THE-SHELF ORTHOTICS.*—Sec-
 2 tion 1834(h)(4)(A) of the Social Security Act (42 U.S.C.
 3 1395m(h)(4)(A)) is amended—

4 (1) in clause (vii), by striking “and” at the end;

5 (2) in clause (viii), by striking “a subsequent
 6 year” and inserting “2003”; and

7 (3) by adding at the end the following new
 8 clauses:

9 “(ix) for each of the years 2004
 10 through 2010—

11 “(I) in the case of orthotics that
 12 have not been custom-fabricated, 0 per-
 13 cent; and

14 “(II) in the case of prosthetics,
 15 prosthetic devices, and custom-fab-
 16 ricated orthotics, the percentage in-
 17 crease described in clause (viii) for the
 18 year involved; and

19 “(x) for 2011 and each subsequent
 20 year, the percentage increase described in
 21 clause (viii) for the year involved;”.

22 (c) *ESTABLISHMENT OF QUALITY STANDARDS AND AC-*
 23 *CREDITATION REQUIREMENTS FOR DURABLE MEDICAL*
 24 *EQUIPMENT PROVIDERS.*—Section 1834(a) (42 U.S.C.
 25 1395m(a)) is amended—

1 (1) *by redesignating paragraph (17), as added*
 2 *by section 4551(c)(1) of the Balanced Budget Act of*
 3 *1997 (111 Stat. 458), as paragraph (19); and*

4 (2) *by adding at the end the following new para-*
 5 *graph:*

6 “(20) *IDENTIFICATION OF QUALITY STAND-*
 7 *ARDS.—*

8 “(A) *IN GENERAL.—Subject to subpara-*
 9 *graph (C), the Secretary shall establish and im-*
 10 *plement quality standards for providers of dura-*
 11 *ble medical equipment throughout the United*
 12 *States that are developed by recognized inde-*
 13 *pendent accreditation organizations (as des-*
 14 *ignated under subparagraph (B)(i)) and with*
 15 *which such providers shall be required to comply*
 16 *in order to—*

17 “(i) *participate in the program under*
 18 *this title;*

19 “(ii) *furnish any item or service de-*
 20 *scribed in subparagraph (D) for which pay-*
 21 *ment is made under this part; and*

22 “(iii) *receive or retain a provider or*
 23 *supplier number used to submit claims for*
 24 *reimbursement for any item or service de-*

1 scribed in subparagraph (D) for which pay-
2 ment may be made under this title.

3 “(B) *DESIGNATION OF INDEPENDENT AC-*
4 *CREDITATION ORGANIZATIONS.*—

5 “(i) *IN GENERAL.*—Not later than the
6 date that is 6 months after the date of en-
7 actment of the Prescription Drug and Medi-
8 care Improvement Act of 2003, the Sec-
9 retary shall designate independent accredi-
10 tation organizations for purposes of sub-
11 paragraph (A).

12 “(ii) *CONSULTATION.*—In determining
13 which independent accreditation organiza-
14 tions to designate under clause (i), the Sec-
15 retary shall consult with an expert outside
16 advisory panel composed of an appropriate
17 selection of representatives of physicians,
18 practitioners, suppliers, and manufacturers
19 to review (and advise the Secretary con-
20 cerning) selection of accrediting organiza-
21 tions and the quality standards of such or-
22 ganizations.

23 “(C) *QUALITY STANDARDS.*—The quality
24 standards described in subparagraph (A) may
25 not be less stringent than the quality standards

1 that would otherwise apply if this paragraph did
 2 not apply and shall include consumer services
 3 standards.

4 “(D) *ITEMS AND SERVICES DESCRIBED.*—
 5 The items and services described in this subpara-
 6 graph are covered items (as defined in para-
 7 graph (13)) for which payment may otherwise be
 8 made under this subsection, other than items
 9 used in infusion, and inhalation drugs used in
 10 conjunction with durable medical equipment.

11 “(E) *PHASED-IN IMPLEMENTATION.*—The
 12 application of the quality standards described in
 13 subparagraph (A) shall be phased-in over a pe-
 14 riod that does not exceed 3 years.”.

15 **SEC. 431. APPLICATION OF COINSURANCE AND DEDUCT-**
 16 **IBLE FOR CLINICAL DIAGNOSTIC LABORA-**
 17 **TORY TESTS.**

18 (a) *COINSURANCE.*—

19 (1) *IN GENERAL.*—Section 1833(a) (42 U.S.C.
 20 1395l(a)) is amended—

21 (A) in paragraph (1)(D)(i), by striking “(or
 22 100 percent, in the case of such tests for which
 23 payment is made on an assignment-related
 24 basis)”; and

1 (B) in paragraph (2)(D)(i), by striking
 2 “(or 100 percent, in the case of such tests for
 3 which payment is made on an assignment-re-
 4 lated basis or to a provider having an agreement
 5 under section 1866)”.

6 (2) *CONFORMING AMENDMENT.*—*The third sen-*
 7 *tence of section 1866(a)(2)(A) of the Social Security*
 8 *Act (42 U.S.C. 1395cc(a)(2)(A) is amended by strik-*
 9 *ing “and with respect to clinical diagnostic labora-*
 10 *tory tests for which payment is made under part B”.*

11 (b) *DEDUCTIBLE.*—*Section 1833(b) of the Social Secu-*
 12 *rity Act (42 U.S.C. 1395l(b)) is amended—*

13 (1) *by striking paragraph (3); and*

14 (2) *by redesignating paragraphs (4), (5), and (6)*
 15 *as paragraphs (3), (4), and (5), respectively.*

16 (c) *EFFECTIVE DATE.*—*The amendments made by this*
 17 *section shall apply to tests furnished on or after January*
 18 *1, 2004.*

19 **SEC. 432. BASING MEDICARE PAYMENTS FOR COVERED**
 20 **OUTPATIENT DRUGS ON MARKET PRICES.**

21 (a) *MEDICARE MARKET BASED PAYMENT AMOUNT.*—
 22 *Section 1842(o) (42 U.S.C. 1395u(o)) is amended—*

23 (1) *in paragraph (1), by striking “equal to 95*
 24 *percent of the average wholesale price.” and inserting*
 25 *“equal to—*

1 “(A) in the case of a drug or biological furnished
2 prior to January 1, 2004, 95 percent of the average
3 wholesale price; and

4 “(B) in the case of a drug or biological furnished
5 on or after January 1, 2004, the payment amount
6 specified in—

7 “(i) in the case of such a drug or biological
8 that is first available for payment under this
9 part on or before April 1, 2003, paragraph (4);
10 and

11 “(ii) in the case of such a drug or biological
12 that is first available for payment under this
13 part after such date, paragraph (5).”; and

14 (2) by adding at the end the following new para-
15 graphs:

16 “(4)(A) Subject to subparagraph (C), the payment
17 amount specified in this paragraph for a year for a drug
18 or biological is an amount equal to the lesser of—

19 “(i) the average wholesale price for the drug or
20 biological; or

21 “(ii) the amount determined under subpara-
22 graph (B)

23 “(B)(i) Subject to clause (ii), the amount determined
24 under this subparagraph is an amount equal to—

1 “(I) in the case of a drug or biological furnished
2 in 2004, 85 percent of the average wholesale price for
3 the drug or biological (determined as of April 1,
4 2003); and

5 “(II) in the case of a drug or biological furnished
6 in 2005 or a subsequent year, the amount determined
7 under this subparagraph for the previous year in-
8 creased by the percentage increase in the consumer
9 price index for medical care for the 12-month period
10 ending with June of the previous year.

11 “(ii) In the case of a vaccine described in subpara-
12 graph (A) or (B) of section 1861(s)(10), the amount deter-
13 mined under this subparagraph is an amount equal to the
14 average wholesale price for the drug or biological.

15 “(C)(i) The Secretary shall establish a process under
16 which the Secretary determines, for such drugs or
17 biologicals as the Secretary determines appropriate, wheth-
18 er the widely available market price to physicians or sup-
19 pliers for the drug or biological furnished in a year is dif-
20 ferent from the payment amount established under subpara-
21 graph (B) for the year. Such determination shall be based
22 on the information described in clause (ii) as the Secretary
23 determines appropriate.

24 “(ii) The information described in this clause is the
25 following information:

1 “(I) Any report on drug or biological market
2 prices by the Inspector General of the Department of
3 Health and Human Services or the Comptroller Gen-
4 eral of the United States that is made available after
5 December 31, 1999.

6 “(II) A review of drug or biological market
7 prices by the Secretary, which may include informa-
8 tion on such market prices from insurers, private
9 health plans, manufacturers, wholesalers, distributors,
10 physician supply houses, specialty pharmacies, group
11 purchasing arrangements, physicians, suppliers, or
12 any other source the Secretary determines appro-
13 priate.

14 “(III) Data and information submitted by the
15 manufacturer of the drug or biological or by another
16 entity.

17 “(IV) Other data and information as determined
18 appropriate by the Secretary.

19 “(iii) If the Secretary makes a determination under
20 clause (i) with respect to the widely available market price
21 for a drug or biological for a year, the following provisions
22 shall apply:

23 “(I) Subject to clause (iv), the amount deter-
24 mined under this subparagraph shall be substituted
25 for the amount determined under subparagraph (B)

1 for purposes of applying subparagraph (A)(ii)(I) for
2 the year and all subsequent years.

3 “(II) The Secretary may make subsequent deter-
4 minations under clause (i) with respect to the widely
5 available market price for the drug or biological.

6 “(III) If the Secretary does not make a subse-
7 quent determination under clause (i) with respect to
8 the widely available market price for the drug or bio-
9 logical for a year, the amount determined under this
10 subparagraph shall be an amount equal to the
11 amount determined under this subparagraph for the
12 previous year increased by the percentage increase de-
13 scribed in subparagraph (B)(i)(II) for the year in-
14 volved.

15 “(iv) If the first determination made under clause (i)
16 with respect to the widely available market price for a drug
17 or biological would result in a payment amount in a year
18 that is more than 15 percent less than the amount deter-
19 mined under subparagraph (B) for the drug or biological
20 for the previous year (or, for 2004, the payment amount
21 determined under paragraph (1)(A), determined as of April
22 1, 2003), the Secretary shall provide for a transition to the
23 amount determined under clause (i) so that the payment
24 amount is reduced in annual increments equal to 15 per-
25 cent of the payment amount in such previous year until

1 *the payment amount is equal to the amount determined*
 2 *under clause (i), as increased each year by the percentage*
 3 *increase described in subparagraph (B)(i)(II) for the year.*
 4 *The preceding sentence shall not apply to a drug or biologi-*
 5 *cal where a generic version of the drug or biological first*
 6 *enters the market on or after January 1, 2004 (even if the*
 7 *generic version of the drug or biological is not marketed*
 8 *under the chemical name of such drug or biological).*

9 “(5) *In the case of a drug or biological that is first*
 10 *available for payment under this part after April 1, 2003,*
 11 *the following rules shall apply:*

12 “(A) *As a condition of obtaining a code to report*
 13 *such new drug or biological and to receive payment*
 14 *under this part, a manufacturer shall provide the*
 15 *Secretary (in a time, manner, and form approved by*
 16 *the Secretary) with data and information on prices*
 17 *at which the manufacturer estimates physicians and*
 18 *suppliers will be able to routinely obtain the drug or*
 19 *biological in the market during the first year that the*
 20 *drug or biological is available for payment under this*
 21 *part and such additional information that the manu-*
 22 *facturer determines appropriate.*

23 “(B) *During the year that the drug or biological*
 24 *is first available for payment under this part, the*
 25 *manufacturer of the drug or biological shall provide*

1 *the Secretary (in a time, manner, and form approved*
 2 *by the Secretary) with updated information on the*
 3 *actual market prices paid by such physicians or sup-*
 4 *pliers for the drug or biological in the year.*

5 *“(C) The amount specified in this paragraph for*
 6 *a drug or biological for the year described in subpara-*
 7 *graph (B) is equal to an amount determined by the*
 8 *Secretary based on the information provided under*
 9 *subparagraph (A) and other information that the Sec-*
 10 *retary determines appropriate.*

11 *“(D) The amount specified in this paragraph for*
 12 *a drug or biological for the year after the year de-*
 13 *scribed in subparagraph (B) is equal to an amount*
 14 *determined by the Secretary based on the information*
 15 *provided under subparagraph (B) and other informa-*
 16 *tion that the Secretary determines appropriate.*

17 *“(E) The amount specified in this paragraph for*
 18 *a drug or biological for the year beginning after the*
 19 *year described in subparagraph (D) and each subse-*
 20 *quent year is equal to the lesser of—*

21 *“(i) the average wholesale price for the drug*
 22 *or biological; or*

23 *“(ii) the amount determined—*

24 *“(I) by the Secretary under paragraph*
 25 *(4)(C)(i) with respect to the widely avail-*

able market price for the drug or biological for the year, if such paragraph was applied by substituting ‘the payment determined under paragraph (5)(E)(ii)(II) for the year’ for ‘established under subparagraph (B) for the year’; and

“(II) if no determination described in subclause (I) is made for the drug or biological for the year, under this subparagraph with respect to the drug or biological for the previous year increased by the percentage increase described in paragraph (4)(B)(i)(II) for the year involved.”.

(b) *ADJUSTMENTS TO PAYMENT AMOUNTS FOR ADMINISTRATION OF DRUGS AND BIOLOGICALS.*—

(1) *ADJUSTMENT IN PHYSICIAN PRACTICE EXPENSE RELATIVE VALUE UNITS.*—Section 1848(c)(2) (42 U.S.C. 1395w-4(c)(2)) is amended—

(A) in subparagraph (B)—

(i) in clause (ii)(II), by striking “The adjustments” and inserting “Subject to clause (iv), the adjustments”; and

(ii) by adding at the end the following new clause:

1 “(iv) *EXEMPTION FROM BUDGET NEU-*
 2 *TRALITY IN 2004.*—Any additional expendi-
 3 *tures under this part that are attributable*
 4 *to subparagraph (H) shall not be taken into*
 5 *account in applying clause (ii)(II) for*
 6 *2004.”; and*

7 *(B) by adding at the end the following new*
 8 *subparagraph:*

9 “(H) *ADJUSTMENTS IN PRACTICE EXPENSE*
 10 *RELATIVE VALUE UNITS FOR DRUG ADMINISTRA-*
 11 *TION SERVICES FOR 2004.*—In establishing the
 12 *physician fee schedule under subsection (b) with*
 13 *respect to payments for services furnished in*
 14 *2004, the Secretary shall, in determining prac-*
 15 *tice expense relative value units under this sub-*
 16 *section, utilize a survey submitted to the Sec-*
 17 *retary as of January 1, 2003, by a physician*
 18 *specialty organization pursuant to section 212 of*
 19 *the Medicare, Medicaid, and SCHIP Balanced*
 20 *Budget Refinement Act of 1999 if the survey—*

21 “(i) *covers practice expenses for oncol-*
 22 *ogy administration services; and*

23 “(ii) *meets criteria established by the*
 24 *Secretary for acceptance of such surveys.”.*

1 (2) *PAYMENT FOR MULTIPLE CHEMOTHERAPY*
 2 *AGENTS FURNISHED ON A SINGLE DAY THROUGH THE*
 3 *PUSH TECHNIQUE.*—

4 (A) *REVIEW OF POLICY.*—*The Secretary*
 5 *shall review the policy, as in effect on the date*
 6 *of enactment of this Act, with respect to payment*
 7 *under section 1848 of the Social Security Act (42*
 8 *U.S.C. 1395w-4) for the administration of more*
 9 *than 1 anticancer chemotherapeutic agent to an*
 10 *individual on a single day through the push*
 11 *technique.*

12 (B) *MODIFICATION OF POLICY.*—*After con-*
 13 *ducting the review under subparagraph (A), the*
 14 *Secretary shall modify such payment policy if*
 15 *the Secretary determines such modification to be*
 16 *appropriate.*

17 (C) *EXEMPTION FROM BUDGET NEUTRALITY*
 18 *UNDER PHYSICIAN FEE SCHEDULE.*—*If the Sec-*
 19 *retary modifies such payment policy pursuant to*
 20 *subparagraph (B), any increased expenditures*
 21 *under title XVIII of the Social Security Act re-*
 22 *sulting from such modification shall be treated*
 23 *as additional expenditures attributable to sub-*
 24 *paragraph (H) of section 1848(c)(2) of the Social*
 25 *Security Act (42 U.S.C. 1395w-4(c)(2)), as*

added by paragraph (1)(B), for purposes of applying the exemption to budget neutrality under subparagraph (B)(iv) of such section, as added by paragraph (1)(A).

(3) *TREATMENT OF OTHER SERVICES CURRENTLY IN THE NONPHYSICIAN WORK POOL.*—The Secretary shall make adjustments to the nonphysician work pool methodology (as such term is used in the final rule promulgated by the Secretary in the Federal Register on December 31, 2002 (67 Fed. Reg. 251)), for the determination of practice expense relative value units under the physician fee schedule under section 1848(c)(2)(C)(ii) of the Social Security Act (42 U.S.C. 1395w–4(c)(2)(C)(ii)), so that the practice expense relative value units for services determined under such methodology are not disproportionately reduced relative to the practice expense relative value units of services not determined under such methodology, as a result of the amendments to such Act made by paragraph (1).

(4) *ADMINISTRATION OF BLOOD CLOTTING FACTORS.*—Section 1842(o) (42 U.S.C. 1395u(o)), as amended by subsection (a)(2), is amended by adding at the end the following new paragraph:

1 “(6)(A) *Subject to subparagraph (B), in the case of*
2 *clotting factors furnished on or after January 1, 2004, the*
3 *Secretary shall, after reviewing the January 2003 report*
4 *to Congress by the Comptroller General of the United States*
5 *entitled ‘Payment for Blood Clotting Factor Exceeds Pro-*
6 *viders Acquisition Cost’ (GAO–03–184), provide for a sepa-*
7 *rate payment for the administration of such blood clotting*
8 *factors in an amount that the Secretary determines to be*
9 *appropriate.*

10 “(B) *In determining the separate payment amount*
11 *under subparagraph (A) for blood clotting factors furnished*
12 *in 2004, the Secretary shall ensure that the total amount*
13 *of payments under this part (as estimated by the Secretary)*
14 *for such factors under paragraphs (4) and (5) and such sep-*
15 *arate payments for such factors does not exceed the total*
16 *amount of payments that would have been made for such*
17 *factors under this part (as estimated by the Secretary) if*
18 *the amendments made by section 433 of the Prescription*
19 *Drug and Medicare Improvement Act of 2003 had not been*
20 *enacted.*

21 “(C) *The separate payment amount under this sub-*
22 *paragraph for blood clotting factors furnished in 2005 or*
23 *a subsequent year shall be equal to the separate payment*
24 *amount determined under this paragraph for the previous*

1 *year increased by the percentage increase described in para-*
 2 *graph (4)(B)(i)(II) for the year involved.”.*

3 (5) *INCREASE IN COMPOSITE RATE FOR END*
 4 *STAGE RENAL DISEASE FACILITIES.—Section 1881(b)*
 5 *(42 U.S.C. 1395rr(b) is amended—*

6 (A) *in paragraph (7), by adding at the end*
 7 *the following new sentence: “In the case of dialy-*
 8 *sis services furnished in 2004 or a subsequent*
 9 *year, the composite rate for such services shall be*
 10 *determined under paragraph (12).”;* and

11 (B) *by adding at the end the following new*
 12 *paragraph:*

13 “(12)(A) *In the case of dialysis services furnished dur-*
 14 *ing 2004, the composite rate for such services shall be the*
 15 *composite rate that would otherwise apply under paragraph*
 16 *(7) for the year increased by an amount to ensure (as esti-*
 17 *mated by the Secretary) that—*

18 “(i) *the sum of the total amount of—*

19 “(I) *the composite rate payments for such*
 20 *services for the year, as increased under this*
 21 *paragraph; and*

22 “(II) *the payments for drugs and biologicals*
 23 *(other than erythropoetin) furnished in connec-*
 24 *tion with the furnishing of renal dialysis services*
 25 *and separately billed by renal dialysis facilities*

1 under paragraphs (4) and (5) of section 1842(o)
2 for the year; is equal to

3 “(ii) the sum of the total amount of the com-
4 posite rate payments under paragraph (7) for the
5 year and the payments for the separately billed drugs
6 and biologicals described in clause (i)(II) that would
7 have been made if the amendments made by section
8 433 of the Prescription Drug and Medicare Improve-
9 ment Act of 2003 had not been enacted.

10 “(B) Subject to subparagraph (E), in the case of dialy-
11 sis services furnished in 2005, the composite rate for such
12 services shall be an amount equal to the composite rate es-
13 tablished under subparagraph (A), increased by 0.05 per-
14 cent and further increased by 1.6 percent.

15 “(C) Subject to subparagraph (E), in the case of dialy-
16 sis services furnished in 2006, the composite rate for such
17 services shall be an amount equal to the composite rate es-
18 tablished under subparagraph (B), increased by 0.05 per-
19 cent and further increased by 1.6 percent.

20 “(D) Subject to subparagraph (E), in the case of dialy-
21 sis services furnished in 2007 and all subsequent years, the
22 composite rate for such services shall be an amount equal
23 to the composite rate established under this paragraph for
24 the previous year, increased by 0.05 percent.

1 “(E) If the Secretary implements a reduction in the
2 payment amount under paragraph (4)(C) or (5) for a drug
3 or biological described in subparagraph (A)(i)(II) for a
4 year after 2004, the Secretary shall, as estimated by the
5 Secretary—

6 “(i) increase the composite rate for dialysis serv-
7 ices furnished in such year in the same manner that
8 the composite rate for such services for 2004 was in-
9 creased under subparagraph (A); and

10 “(ii) increase the percentage increase under sub-
11 paragraph (C) or (D) (as applicable) for years after
12 the year described in clause (i) to ensure that such in-
13 creased percentage would result in expenditures equal
14 to the sum of the total composite rate payments for
15 such services for such years and the total payments
16 for drugs and biologicals described in subparagraph
17 (A)(i)(II) is equal to the sum of the total amount of
18 the composite rate payments under this paragraph for
19 such years and the payments for the drugs and
20 biologicals described in subparagraph (A)(i)(II) that
21 would have been made if the reduction in payment
22 amount described in subparagraph had not been
23 made.

24 “(F) There shall be no administrative or judicial re-
25 view under section 1869, section 1878, or otherwise, of de-

1 terminations of payment amounts, methods, or adjustments
 2 under this paragraph.”.

3 (6) *HOME INFUSION DRUGS*.—Section 1842(o)
 4 (42 U.S.C. 1395u(o)), as amended by subsection
 5 (a)(2) and paragraph (4), is amended by adding at
 6 the end the following new paragraph:

7 “(7)(A) Subject to subparagraph (B), in the case of
 8 infusion drugs and biologicals furnished through an item
 9 of durable medical equipment covered under section 1861(n)
 10 on or after January 1, 2004, the Secretary may make sepa-
 11 rate payments for furnishing such drugs and biologicals in
 12 an amount determined by the Secretary if the Secretary de-
 13 termines such separate payment to be appropriate.

14 “(B) In determining the amount of any separate pay-
 15 ment under subparagraph (A) for a year, the Secretary
 16 shall ensure that the total amount of payments under this
 17 part for such infusion drugs and biologicals for the year
 18 and such separate payments for the year does not exceed
 19 the total amount of payments that would have been made
 20 under this part for the year for such infusion drugs and
 21 biologicals if section 433 of the Prescription Drug and
 22 Medicare Improvement Act of 2003 had not been enacted.”.

23 (7) *INHALATION DRUGS*.—Section 1842(o) (42
 24 U.S.C. 1395u(o)), as amended by subsection (a)(2)

1 *and paragraphs (4) and (6), is amended by adding*
 2 *at the end the following new paragraph:*

3 *“(8)(A) Subject to subparagraph (B), in the case of*
 4 *inhalation drugs and biologicals furnished through durable*
 5 *medical equipment covered under section 1861(n) on or*
 6 *after January 1, 2004, the Secretary may increase pay-*
 7 *ments for such equipment under section 1834(a) and may*
 8 *make separate payments for furnishing such drugs and*
 9 *biologicals if the Secretary determines such increased or*
 10 *separate payments are necessary to appropriately furnish*
 11 *such equipment and drugs and biologicals to beneficiaries.*

12 *“(B) The total amount of any increased payments and*
 13 *separate payments under subparagraph (A) for a year may*
 14 *not exceed an amount equal to 10 percent of the amount*
 15 *(as estimated by the Secretary) by which—*

16 *“(i) the total amount of payments that would*
 17 *have been made for such drugs and biologicals for the*
 18 *year if section 433 of the Prescription Drug and*
 19 *Medicare Improvement Act of 2003 had not been en-*
 20 *acted; exceeds*

21 *“(ii) the total amount of payments for such*
 22 *drugs and biologicals under paragraphs (4) and (5).”.*

23 *(8) PHARMACY DISPENSING FEE FOR CERTAIN*
 24 *DRUGS AND BIOLOGICALS.—Section 1842(o)(2) (42*
 25 *U.S.C. 1395u(o)(2)) is amended to read as follows:*

1 “(2) If payment for a drug or biological is made to
 2 a licensed pharmacy approved to dispense drugs or
 3 biologicals under this part, the Secretary—

4 “(A) in the case of an immunosuppressive drug
 5 described in subparagraph (J) of section 1861(s)(2)
 6 and an oral drug described in subparagraph (Q) or
 7 (T) of such section, shall pay a dispensing fee deter-
 8 mined appropriate by the Secretary (less the applica-
 9 ble deductible and coinsurance amounts) to the phar-
 10 macy; and

11 “(B) in the case of a drug or biological not de-
 12 scribed in subparagraph (A), may pay a dispensing
 13 fee determined appropriate by the Secretary (less the
 14 applicable deductible and coinsurance amounts) to the
 15 pharmacy.”.

16 (9) PAYMENT FOR CHEMOTHERAPY DRUGS PUR-
 17 CHASED BUT NOT ADMINISTERED BY PHYSICIANS.—
 18 Section 1842(o) (42 U.S.C. 1395u(o)), as amended by
 19 subsection (a)(2) and paragraphs (4), (6) and (7), is
 20 amended by adding at the end the following new
 21 paragraph:

22 “(9)(A) Subject to subparagraph (B), the Sec-
 23 retary may increase (in an amount determined ap-
 24 propriate) the amount of payments to physicians for
 25 anticancer chemotherapeutic drugs or biologicals that

1 *would otherwise be made under this part in order to*
2 *compensate such physicians for anticancer*
3 *chemotherapeutic drugs or biologicals that are pur-*
4 *chased by physicians with a reasonable intent to ad-*
5 *minister to an individual enrolled under this part but*
6 *which cannot be administered to such individual de-*
7 *spite the reasonable efforts of the physician.*

8 *“(B) The total amount of increased payments*
9 *made under subparagraph (A) in a year (as esti-*
10 *mated by the Secretary) may not exceed an amount*
11 *equal to 1 percent of the total amount of payments*
12 *made under paragraphs (4) and (5) for such*
13 *anticancer chemotherapeutic drugs or biologicals fur-*
14 *nished by physicians in such year (as estimated by*
15 *the Secretary).”.*

16 *(c) LINKAGE OF REVISED DRUG PAYMENTS AND IN-*
17 *CREASES FOR DRUG ADMINISTRATION.—The Secretary*
18 *shall not implement the revisions in payment amounts for*
19 *a category of drug or biological as a result of the amend-*
20 *ments made by subsection (a) unless the Secretary concur-*
21 *rently implements the adjustments to payment amounts for*
22 *administration of such category of drug or biological for*
23 *which the Secretary is required to make an adjustment, as*
24 *specified in the amendments made by, and provisions of,*
25 *subsection (b).*

1 (d) *PROHIBITION OF ADMINISTRATIVE AND JUDICIAL*
 2 *REVIEW.*—

3 (1) *DRUGS.*—Section 1842(o) (42 U.S.C.
 4 1395u(o)), as amended by subsection (a)(2) and para-
 5 graphs (4), (6), (7), and (9) of subsection (b), is
 6 amended by adding at the end the following new
 7 paragraph:

8 “(10) *There shall be no administrative or judicial re-*
 9 *view under section 1869, section 1878, or otherwise, of de-*
 10 *terminations of payment amounts, methods, or adjustments*
 11 *under paragraph (2) or paragraphs (4) through (9).”*

12 (2) *PHYSICIAN FEE SCHEDULE.*—Section
 13 1848(i)(1) (42 U.S.C. 1395w-4(i)(1)) is amended—

14 (A) in subparagraph (D), by striking “and”
 15 at the end;

16 (B) in subparagraph (E), by striking the
 17 period at the end and inserting “, and”; and

18 (C) by adding at the end the following new
 19 subparagraph:

20 “(F) *adjustments in practice expense rel-*
 21 *ative value units under subsection (c)(2)(H).*”.

22 (3) *MULTIPLE CHEMOTHERAPY AGENTS AND*
 23 *OTHER SERVICES CURRENTLY ON THE NON-PHYSICIAN*
 24 *WORK POOL.*—*There shall be no administrative or ju-*
 25 *dicial review under section 1869, section 1878, or oth-*

erwise, of determinations of payment amounts, methods, or adjustments under paragraphs (2) and (3) of subsection (b).

(e) *STUDIES AND REPORTS.*—

(1) *GAO STUDY AND REPORT ON BENEFICIARY ACCESS TO DRUGS AND BIOLOGICALS.*—

(A) *STUDY.*—The Comptroller General of the United States shall conduct a study that examines the impact the provisions of, and the amendments made by, this section have on access by medicare beneficiaries to drugs and biologicals covered under the medicare program.

(B) *REPORT.*—Not later than January 1, 2006, the Comptroller General shall submit a report to Congress on the study conducted under subparagraph (A) together with such recommendations as the Comptroller General determines to be appropriate.

(2) *STUDY AND REPORT BY THE HHS INSPECTOR GENERAL ON MARKET PRICES OF DRUGS AND BIOLOGICALS.*—

(A) *STUDY.*—The Inspector General of the Department of Health and Human Services shall conduct 1 or more studies that—

1 (i) examine the market prices that
 2 drugs and biologicals covered under the
 3 medicare program are widely available to
 4 physicians and suppliers; and

5 (ii) compare such widely available
 6 market prices to the payment amount for
 7 such drugs and biologicals under section
 8 1842(o) of the Social Security Act (42
 9 U.S.C. 1395u(o).

10 (B) *REQUIREMENT.*—In conducting the
 11 study under subparagraph (A), the Inspector
 12 General shall focus on those drugs and
 13 biologicals that represent the largest portions of
 14 expenditures under the medicare program for
 15 drugs and biologicals.

16 (C) *REPORT.*—The Inspector General shall
 17 prepare a report on any study conducted under
 18 subparagraph (A).

19 **SEC. 433. INDEXING PART B DEDUCTIBLE TO INFLATION.**

20 The first sentence of section 1833(b) (42 U.S.C.
 21 1395l(b)) is amended by striking “and \$100 for 1991 and
 22 subsequent years” and inserting the following: “, \$100 for
 23 1991 through 2005, \$125 for 2006, and for 2007 and there-
 24 after, the amount in effect for the previous year, increase
 25 by the percentage increase in the consumer price index for

1 *all urban consumers (U.S. city average) for the 12-month*
 2 *period ending with June of the previous year, rounded to*
 3 *the nearest dollar”.*

4 **SEC. 434. REVISIONS TO REASSIGNMENT PROVISIONS.**

5 (a) *IN GENERAL.*—Section 1842(b)(6)(A)(ii) (42
 6 U.S.C. 1395u(b)(6)(A)(ii)) is amended to read as follows:
 7 “(ii) where the service was provided under a contractual
 8 arrangement between such physician or other person and
 9 an entity (as defined by the Secretary), to the entity if
 10 under such arrangement such entity submits the bill for
 11 such service and such arrangement meets such program in-
 12 tegrity and other safeguards as the Secretary may deter-
 13 mine to be appropriate,”.

14 (b) *CONFORMING AMENDMENT.*—The second sentence
 15 of section 1842(b)(6) (42 U.S.C. 1395u(b)(6)) is amended
 16 by striking “except to an employer or facility as described
 17 in clause (A)” and inserting “except to an employer or enti-
 18 ty as described in subparagraph (A)”.

19 (c) *EFFECTIVE DATE.*—The amendments made by this
 20 section shall apply to payments made on or after the date
 21 of enactment of this Act.

1 **SEC. 435. EXTENSION OF TREATMENT OF CERTAIN PHYSI-**
 2 **CIAN PATHOLOGY SERVICES UNDER MEDI-**
 3 **CARE.**

4 *Section 542(c) of BIPA (114 Stat. 2763A–551) is*
 5 *amended by inserting “, and for services furnished during*
 6 *2005” before the period at the end.*

7 **SEC. 436. ADEQUATE REIMBURSEMENT FOR OUTPATIENT**
 8 **PHARMACY THERAPY UNDER THE HOSPITAL**
 9 **OUTPATIENT PPS.**

10 *(a) SPECIAL RULES FOR DRUGS AND BIOLOGICALS.—*
 11 *Section 1833(t) (42 U.S.C. 1395(t)) is amended—*

12 *(1) by redesignating paragraph (13) as para-*
 13 *graph (14); and*

14 *(2) by inserting after paragraph (12) the fol-*
 15 *lowing new paragraph:*

16 *“(13) SPECIAL RULES FOR CERTAIN DRUGS AND*
 17 *BIOLOGICALS.—*

18 *“(A) BEFORE 2007.—*

19 *“(i) IN GENERAL.—Notwithstanding*
 20 *paragraph (6), but subject to clause (ii),*
 21 *with respect to a separately payable drug or*
 22 *biological described in subparagraph (D)*
 23 *furnished on or after January 1, 2005, and*
 24 *before January 1, 2007, hospitals shall be*
 25 *reimbursed as follows:*

1 “(I) *DRUGS AND BIOLOGICALS*
2 *FURNISHED AS PART OF A CURRENT*
3 *OPD SERVICE.*—*The amount of pay-*
4 *ment for a drug or biological described*
5 *in subparagraph (D) provided as a*
6 *part of a service that was a covered*
7 *OPD service on May 1, 2003, shall be*
8 *the applicable percentage (as defined*
9 *in subparagraph (C)) of the average*
10 *wholesale price for the drug or biologi-*
11 *cal that would have been determined*
12 *under section 1842(o) on such date.*

13 “(II) *DRUGS AND BIOLOGICALS*
14 *FURNISHED AS PART OF OTHER OPD*
15 *SERVICES.*—*The amount of payment*
16 *for a drug or biological described in*
17 *subparagraph (D) provided as part of*
18 *any other covered OPD service shall be*
19 *the applicable percentage (as defined*
20 *in subparagraph (C)) of the average*
21 *wholesale price that would have been*
22 *determined under section 1842(o) on*
23 *May 1, 2003, if payment for such a*
24 *drug or biological could have been*
25 *made under this part on that date.*

1 “(ii) *UPDATE FOR 2006.*—*For 2006, the*
 2 *amounts determined under clauses (i) and*
 3 *(ii) shall be the amount established for 2005*
 4 *increased by the percentage increase in the*
 5 *Consumer Price Index for all urban con-*
 6 *sumers (U.S. urban average) for the 12-*
 7 *month period ending with June of the pre-*
 8 *vious year.*

9 “(B) *AFTER 2007.*—

10 “(i) *ONGOING STUDY AND REPORTS ON*
 11 *ADEQUATE REIMBURSEMENTS.*—

12 “(I) *STUDY.*—*The Secretary shall*
 13 *contract with an eligible organization*
 14 *(as defined in subclause (IV)) to con-*
 15 *duct a study to determine the hospital*
 16 *acquisition, pharmacy services, and*
 17 *handling costs for each individual drug*
 18 *or biological described in subparagraph*
 19 *(D).*

20 “(II) *STUDY REQUIREMENTS.*—
 21 *The study conducted under subclause*
 22 *(I) shall—*

23 “(aa) *be accurate to within 3*
 24 *percent of true mean hospital ac-*
 25 *quisition and handling costs for*

1 each drug and biological at the 95
2 percent confidence level;

3 “(bb) begin not later than
4 January 1, 2005; and

5 “(cc) be updated annually
6 for changes in hospital costs and
7 the addition of newly marketed
8 products.

9 “(III) *REPORTS.*—Not later than
10 January 1 of each year (beginning
11 with 2006), the Secretary shall submit
12 to Congress a report on the study con-
13 ducted under clause (i) together with
14 recommendations for such legislative or
15 administrative action as the Secretary
16 determines to be appropriate.

17 “(IV) *ELIGIBLE ORGANIZATION*
18 *DEFINED.*—In this clause, the term ‘el-
19 igible organization’ means a private,
20 nonprofit organization within the
21 meaning of section 501(c) of the Inter-
22 nal Revenue Code.

23 “(ii) *ESTABLISHMENT OF PAYMENT*
24 *METHODOLOGY.*—Notwithstanding para-
25 graph (6), the Secretary, in establishing a

1 *payment methodology on or after the date of*
2 *enactment of the Prescription Drug and*
3 *Medicare Improvement Act of 2003, shall*
4 *take into consideration the findings of the*
5 *study conducted under clause (i)(I) in de-*
6 *termining payment amounts for each drug*
7 *and biological provided as part of a covered*
8 *OPD service furnished on or after January*
9 *1, 2007.*

10 “(C) *APPLICABLE PERCENTAGE DEFINED.*—

11 *In this paragraph, the term ‘applicable percent-*
12 *age’ means—*

13 “(i) *with respect to a biological prod-*
14 *uct (approved under a biologics license ap-*
15 *plication under section 351 of the Public*
16 *Health Service Act), a single source drug*
17 *(as defined in section 1927(k)(7)(A)(iv)), or*
18 *an orphan product designated under section*
19 *526 of the Food, Drug, and Cosmetic Act to*
20 *which the prospective payment system es-*
21 *tablished under this subsection did not*
22 *apply under the final rule for 2003 pay-*
23 *ments under such system, 94 percent;*

1 “(ii) with respect to an innovator mul-
 2 tiple source drug (as defined in section
 3 1927(k)(7)(A)(ii)), 91 percent; and

4 “(iii) with respect to a noninnovator
 5 multiple source drug (as defined in as de-
 6 fined in section 1927(k)(7)(A)(iii)), 71 per-
 7 cent.

8 “(D) DRUGS AND BIOLOGICALS DE-
 9 SCRIBED.—A drug or biological described in this
 10 paragraph is any drug or biological—

11 “(i) for which the amount of payment
 12 was determined under paragraph (6) prior
 13 to January 1, 2005; and

14 “(ii)(I) which is assigned to a drug
 15 specific ambulatory payment classification
 16 on or after the date of enactment of the Pre-
 17 scription Drug and Medicare Improvement
 18 Act of 2003; or

19 “(II) that would have been reimbursed
 20 under paragraph (6) but for the application
 21 of this paragraph.”.

22 (b) EXCEPTIONS TO BUDGET NEUTRALITY REQUIRE-
 23 MENT.—Section 1833(t)(9)(B) (42 U.S.C. 1395l(t)(9)(B)) is
 24 amended by adding at the end the following: “In deter-
 25 mining the budget neutrality adjustment required by the

1 preceding sentence for fiscal years 2005 and 2006, the Sec-
 2 retary shall not take into account any expenditures that
 3 would not have been made but for the application of para-
 4 graph (13).”.

5 **SEC. 437. LIMITATION OF APPLICATION OF FUNCTIONAL**
 6 **EQUIVALENCE STANDARD.**

7 Section 1833(t)(6) (42 U.S.C. 1395l(t)(6)) is amended
 8 by adding at the end the following new subparagraph:

9 “(F) *LIMITATION OF APPLICATION OF FUNC-*
 10 *TIONAL EQUIVALENCE STANDARD.—*

11 “(i) *IN GENERAL.—The Secretary may*
 12 *not publish regulations that apply a func-*
 13 *tional equivalence standard to a drug or bi-*
 14 *ological under this paragraph.*

15 “(ii) *APPLICATION.—Paragraph (1)*
 16 *shall apply to the application of a func-*
 17 *tional equivalence standard to a drug or bi-*
 18 *ological on or after the date of enactment of*
 19 *the Prescription Drug and Medicare Im-*
 20 *provement Act of 2003 unless—*

21 “(I) *such application was being*
 22 *made to such drug or biological prior*
 23 *to such date of enactment; and*

24 “(II) *the Secretary applies such*
 25 *standard to such drug or biological*

1 *only for the purpose of determining eli-*
 2 *gibility of such drug or biological for*
 3 *additional payments under this para-*
 4 *graph and not for the purpose of any*
 5 *other payments under this title.*

6 “(iii) *RULE OF CONSTRUCTION.*—*Noth-*
 7 *ing in this subparagraph shall be construed*
 8 *to effect the Secretary’s authority to deem a*
 9 *particular drug to be identical to another*
 10 *drug if the 2 products are pharmaceutically*
 11 *equivalent and bioequivalent, as determined*
 12 *by the Commissioner of Food and Drugs.*

13 **SEC. 438. MEDICARE COVERAGE OF ROUTINE COSTS ASSO-**
 14 **CIATED WITH CERTAIN CLINICAL TRIALS.**

15 (a) *IN GENERAL.*—*With respect to the coverage of rou-*
 16 *tine costs of care for beneficiaries participating in a quali-*
 17 *fying clinical trial, as set forth on the date of the enactment*
 18 *of this Act in National Coverage Determination 30–1 of the*
 19 *Medicare Coverage Issues Manual, the Secretary shall deem*
 20 *clinical trials conducted in accordance with an investiga-*
 21 *tional device exemption approved under section 520(g) of*
 22 *the Federal Food, Drug, and Cosmetic Act (42 U.S.C.*
 23 *360j(g)) to be automatically qualified for such coverage.*

24 (b) *RULE OF CONSTRUCTION.*—*Nothing in this section*
 25 *shall be construed as authorizing or requiring the Secretary*

1 to modify the regulations set forth on the date of the enact-
 2 ment of this Act at subpart B of part 405 of title 42, Code
 3 of Federal Regulations, or subpart A of part 411 of such
 4 title, relating to coverage of, and payment for, a medical
 5 device that is the subject of an investigational device exemp-
 6 tion by the Food and Drug Administration (except as may
 7 be necessary to implement subsection (a)).

8 (c) *LIMITATION OF EXPENDITURES IN YEARS PRIOR*
 9 *TO 2014.*—

10 (1) *IN GENERAL.*—*The Secretary shall ensure*
 11 *that the total amount of expenditures under title*
 12 *XVIII of the Social Security Act (including amounts*
 13 *expended by reason of this section) in a year prior to*
 14 *2014 does not exceed the sum of—*

15 (A) *the total amount of expenditures under*
 16 *such title XVIII that would have made if this*
 17 *section had not been enacted; and*

18 (B) *the applicable amount.*

19 (2) *APPLICABLE AMOUNT.*—*For purposes of*
 20 *paragraph (1), the term “applicable amount”*
 21 *means—*

22 (A) *for 2005, \$32,000,000;*

23 (B) *for 2006, \$34,000,000;*

24 (C) *for 2007, \$36,000,000;*

25 (D) *for 2008, \$38,000,000;*

- 1 (E) for 2009, \$40,000,000;
 2 (F) for 2010, \$42,000,000;
 3 (G) for 2011, \$44,000,000;
 4 (H) for 2012, \$48,000,000; and
 5 (I) for 2013, \$50,000,000.

6 (3) *STEPS TO ENSURE FUNDING LIMITATION NOT*
 7 *VIOLATED.*—If the Secretary determines that the ap-
 8 plication of this section will result in the funding
 9 limitation described in paragraph (1) being violated
 10 for any year, the Secretary shall take appropriate
 11 steps to stay within such funding limitation, includ-
 12 ing through limiting the number of clinical trials
 13 deemed under subsection (a) and only covering a por-
 14 tion of the routine costs described in such subsection.
 15 (d) *EFFECTIVE DATE.*—This section shall apply to
 16 clinical trials begun on or after January 1, 2005.

17 **SEC. 439. WAIVER OF PART B LATE ENROLLMENT PENALTY**
 18 **FOR CERTAIN MILITARY RETIREES; SPECIAL**
 19 **ENROLLMENT PERIOD.**

20 (a) *WAIVER OF PENALTY.*—

21 (1) *IN GENERAL.*—Section 1839(b) (42 U.S.C.
 22 1395r(b)) is amended by adding at the end the fol-
 23 lowing new sentence: “No increase in the premium
 24 shall be effected for a month in the case of an indi-
 25 vidual who is 65 years of age or older, who enrolls

1 *under this part during 2002, 2003, 2004, or 2005 and*
 2 *who demonstrates to the Secretary before December*
 3 *31, 2005, that the individual is a covered beneficiary*
 4 *(as defined in section 1072(5) of title 10, United*
 5 *States Code). The Secretary shall consult with the*
 6 *Secretary of Defense in identifying individuals de-*
 7 *scribed in the previous sentence.”.*

8 (2) *EFFECTIVE DATE.*—*The amendment made by*
 9 *paragraph (1) shall apply to premiums for months*
 10 *beginning with January 2005. The Secretary shall es-*
 11 *tablish a method for providing rebates of premium*
 12 *penalties paid for months on or after January 2005*
 13 *for which a penalty does not apply under such*
 14 *amendment but for which a penalty was previously*
 15 *collected.*

16 (b) *MEDICARE PART B SPECIAL ENROLLMENT PE-*
 17 *RIOD.*—

18 (1) *IN GENERAL.*—*In the case of any individual*
 19 *who, as of the date of enactment of this Act, is 65*
 20 *years of age or older, is eligible to enroll but is not*
 21 *enrolled under part B of title XVIII of the Social Se-*
 22 *curity Act, and is a covered beneficiary (as defined*
 23 *in section 1072(5) of title 10, United States Code), the*
 24 *Secretary shall provide for a special enrollment pe-*
 25 *riod during which the individual may enroll under*

1 *such part. Such period shall begin 1 year after the*
 2 *date of the enactment of this Act and shall end on De-*
 3 *cember 31, 2005.*

4 (2) *COVERAGE PERIOD.—In the case of an indi-*
 5 *vidual who enrolls during the special enrollment pe-*
 6 *riod provided under paragraph (1), the coverage pe-*
 7 *riod under part B of title XVIII of the Social Secu-*
 8 *rity Act shall begin on the first day of the month fol-*
 9 *lowing the month in which the individual enrolls.*

10 **SEC. 440. DEMONSTRATION OF COVERAGE OF CHIRO-**
 11 **PRACTIC SERVICES UNDER MEDICARE.**

12 (a) *DEFINITIONS.—In this section:*

13 (1) *CHIROPRACTIC SERVICES.—The term “chiro-*
 14 *practic services” has the meaning given that term by*
 15 *the Secretary for purposes of the demonstration*
 16 *projects, but shall include, at a minimum—*

17 (A) *care for neuromusculoskeletal conditions*
 18 *typical among eligible beneficiaries; and*

19 (B) *diagnostic and other services that a chi-*
 20 *ropractor is legally authorized to perform by the*
 21 *State or jurisdiction in which such treatment is*
 22 *provided.*

23 (2) *DEMONSTRATION PROJECT.—The term “dem-*
 24 *onstration project” means a demonstration project es-*
 25 *tablished by the Secretary under subsection (b)(1).*

1 (3) *ELIGIBLE BENEFICIARY.*—*The term “eligible*
 2 *beneficiary” means an individual who is enrolled*
 3 *under part B of the medicare program.*

4 (4) *MEDICARE PROGRAM.*—*The term “medicare*
 5 *program” means the health benefits program under*
 6 *title XVIII of the Social Security Act (42 U.S.C. 1395*
 7 *et seq.).*

8 (b) *DEMONSTRATION OF COVERAGE OF CHIROPRACTIC*
 9 *SERVICES UNDER MEDICARE.*—

10 (1) *ESTABLISHMENT.*—*The Secretary shall estab-*
 11 *lish demonstration projects in accordance with the*
 12 *provisions of this section for the purpose of evaluating*
 13 *the feasibility and advisability of covering chiro-*
 14 *practic services under the medicare program (in addi-*
 15 *tion to the coverage provided for services consisting of*
 16 *treatment by means of manual manipulation of the*
 17 *spine to correct a subluxation described in section*
 18 *1861(r)(5) of the Social Security Act (42 U.S.C.*
 19 *1395x(r)(5))).*

20 (2) *NO PHYSICIAN APPROVAL REQUIRED.*—*In es-*
 21 *tablishing the demonstration projects, the Secretary*
 22 *shall ensure that an eligible beneficiary who partici-*
 23 *pates in a demonstration project, including an eligi-*
 24 *ble beneficiary who is enrolled for coverage under a*
 25 *Medicare+Choice plan (or, on and after January 1,*

2006, under a Medicare Advantage plan), is not required to receive approval from a physician or other health care provider in order to receive a chiropractic service under a demonstration project.

(3) *CONSULTATION.*—In establishing the demonstration projects, the Secretary shall consult with chiropractors, organizations representing chiropractors, eligible beneficiaries, and organizations representing eligible beneficiaries.

(4) *PARTICIPATION.*—Any eligible beneficiary may participate in the demonstration projects on a voluntary basis.

(c) *CONDUCT OF DEMONSTRATION PROJECTS.*—

(1) *DEMONSTRATION SITES.*—

(A) *SELECTION OF DEMONSTRATION SITES.*—The Secretary shall conduct demonstration projects at 6 demonstration sites.

(B) *GEOGRAPHIC DIVERSITY.*—Of the sites described in subparagraph (A)—

(i) 3 shall be in rural areas; and

(ii) 3 shall be in urban areas.

(C) *SITES LOCATED IN HPSAS.*—At least 1 site described in clause (i) of subparagraph (B) and at least 1 site described in clause (ii) of such subparagraph shall be located in an area that is

1 *designated under section 332(a)(1)(A) of the*
 2 *Public Health Service Act (42 U.S.C.*
 3 *254e(a)(1)(A)) as a health professional shortage*
 4 *area.*

5 (2) *IMPLEMENTATION; DURATION.—*

6 (A) *IMPLEMENTATION.—The Secretary shall*
 7 *not implement the demonstration projects before*
 8 *October 1, 2004.*

9 (B) *DURATION.—The Secretary shall com-*
 10 *plete the demonstration projects by the date that*
 11 *is 3 years after the date on which the first dem-*
 12 *onstration project is implemented.*

13 (d) *EVALUATION AND REPORT.—*

14 (1) *EVALUATION.—The Secretary shall conduct*
 15 *an evaluation of the demonstration projects—*

16 (A) *to determine whether eligible bene-*
 17 *ficiaries who use chiropractic services use a less-*
 18 *er overall amount of items and services for which*
 19 *payment is made under the medicare program*
 20 *than eligible beneficiaries who do not use such*
 21 *services;*

22 (B) *to determine the cost of providing pay-*
 23 *ment for chiropractic services under the medicare*
 24 *program;*

1 (C) to determine the satisfaction of eligible
 2 beneficiaries participating in the demonstration
 3 projects and the quality of care received by such
 4 beneficiaries; and

5 (D) to evaluate such other matters as the
 6 Secretary determines is appropriate.

7 (2) *REPORT.*—Not later than the date that is 1
 8 year after the date on which the demonstration
 9 projects conclude, the Secretary shall submit to Con-
 10 gress a report on the evaluation conducted under
 11 paragraph (1) together with such recommendations
 12 for legislation or administrative action as the Sec-
 13 retary determines is appropriate.

14 (e) *WAIVER OF MEDICARE REQUIREMENTS.*—The Sec-
 15 retary shall waive compliance with such requirements of the
 16 medicare program to the extent and for the period the Sec-
 17 retary finds necessary to conduct the demonstration
 18 projects.

19 (f) *FUNDING.*—

20 (1) *DEMONSTRATION PROJECTS.*—

21 (A) *IN GENERAL.*—Subject to subparagraph
 22 (B) and paragraph (2), the Secretary shall pro-
 23 vide for the transfer from the Federal Supple-
 24 mentary Insurance Trust Fund under section
 25 1841 of the Social Security Act (42 U.S.C.

1 1395t) of such funds as are necessary for the
 2 costs of carrying out the demonstration projects
 3 under this section.

4 (B) *LIMITATION.*—In conducting the dem-
 5 onstration projects under this section, the Sec-
 6 retary shall ensure that the aggregate payments
 7 made by the Secretary under the medicare pro-
 8 gram do not exceed the amount which the Sec-
 9 retary would have paid under the medicare pro-
 10 gram if the demonstration projects under this
 11 section were not implemented.

12 (2) *EVALUATION AND REPORT.*—There are au-
 13 thorized to be appropriated such sums as are nec-
 14 essary for the purpose of developing and submitting
 15 the report to Congress under subsection (d).

16 **SEC. 441. MEDICARE HEALTH CARE QUALITY DEMONSTRA-**
 17 **TION PROGRAMS.**

18 Title XVIII (42 U.S.C. 1395 et seq.) is amended by
 19 inserting after section 1866B the following new section:

20 “HEALTH CARE QUALITY DEMONSTRATION PROGRAM

21 “SEC. 1866C. (a) *DEFINITIONS.*—In this section:

22 “(1) *BENEFICIARY.*—The term ‘beneficiary’
 23 means a beneficiary who is enrolled in the original
 24 medicare fee-for-service program under parts A and B
 25 or a beneficiary in a staff model or dedicated group
 26 model health maintenance organization under the

1 *Medicare+Choice program (or, on and after January*
 2 *1, 2006, under the MedicareAdvantage program)*
 3 *under part C.*

4 “(2) *HEALTH CARE GROUP.*—

5 “(A) *IN GENERAL.*—*The term ‘health care*
 6 *group’ means—*

7 “(i) *a group of physicians that is orga-*
 8 *nized at least in part for the purpose of*
 9 *providing physician’s services under this*
 10 *title;*

11 “(ii) *an integrated health care delivery*
 12 *system that delivers care through coordi-*
 13 *nated hospitals, clinics, home health agen-*
 14 *cies, ambulatory surgery centers, skilled*
 15 *nursing facilities, rehabilitation facilities*
 16 *and clinics, and employed, independent, or*
 17 *contracted physicians; or*

18 “(iii) *an organization representing re-*
 19 *gional coalitions of groups or systems de-*
 20 *scribed in clause (i) or (ii).*

21 “(B) *INCLUSION.*—*As the Secretary deter-*
 22 *mines appropriate, a health care group may in-*
 23 *clude a hospital or any other individual or enti-*
 24 *ty furnishing items or services for which pay-*
 25 *ment may be made under this title that is affili-*

1 *ated with the health care group under an ar-*
 2 *rangement structured so that such hospital, indi-*
 3 *vidual, or entity participates in a demonstration*
 4 *project under this section.*

5 “(3) *PHYSICIAN.*—*Except as otherwise provided*
 6 *for by the Secretary, the term ‘physician’ means any*
 7 *individual who furnishes services that may be paid*
 8 *for as physicians’ services under this title.*

9 “(b) *DEMONSTRATION PROJECTS.*—*The Secretary*
 10 *shall establish a 5-year demonstration program under*
 11 *which the Secretary shall approve demonstration projects*
 12 *that examine health delivery factors that encourage the de-*
 13 *livery of improved quality in patient care, including—*

14 “(1) *the provision of incentives to improve the*
 15 *safety of care provided to beneficiaries;*

16 “(2) *the appropriate use of best practice guide-*
 17 *lines by providers and services by beneficiaries;*

18 “(3) *reduced scientific uncertainty in the deliv-*
 19 *ery of care through the examination of variations in*
 20 *the utilization and allocation of services, and out-*
 21 *comes measurement and research;*

22 “(4) *encourage shared decision making between*
 23 *providers and patients;*

1 “(5) the provision of incentives for improving the
2 quality and safety of care and achieving the efficient
3 allocation of resources;

4 “(6) the appropriate use of culturally and eth-
5 nically sensitive health care delivery; and

6 “(7) the financial effects on the health care mar-
7 ketplace of altering the incentives for care delivery
8 and changing the allocation of resources.

9 “(c) *ADMINISTRATION BY CONTRACT.*—

10 “(1) *IN GENERAL.*—*Except as otherwise provided*
11 *in this section, the Secretary may administer the*
12 *demonstration program established under this section*
13 *in a manner that is similar to the manner in which*
14 *the demonstration program established under section*
15 *1866A is administered in accordance with section*
16 *1866B.*

17 “(2) *ALTERNATIVE PAYMENT SYSTEMS.*—*A*
18 *health care group that receives assistance under this*
19 *section may, with respect to the demonstration project*
20 *to be carried out with such assistance, include pro-*
21 *posals for the use of alternative payment systems for*
22 *items and services provided to beneficiaries by the*
23 *group that are designed to—*

1 “(A) encourage the delivery of high quality
2 care while accomplishing the objectives described
3 in subsection (b); and

4 “(B) streamline documentation and report-
5 ing requirements otherwise required under this
6 title.

7 “(3) *BENEFITS*.—A health care group that re-
8 ceives assistance under this section may, with respect
9 to the demonstration project to be carried out with
10 such assistance, include modifications to the package
11 of benefits available under the traditional fee-for-serv-
12 ice program under parts A and B or the package of
13 benefits available through a staff model or a dedicated
14 group model health maintenance organization under
15 part C. The criteria employed under the demonstra-
16 tion program under this section to evaluate outcomes
17 and determine best practice guidelines and incentives
18 shall not be used as a basis for the denial of medicare
19 benefits under the demonstration program to patients
20 against their wishes (or if the patient is incompetent,
21 against the wishes of the patient’s surrogate) on the
22 basis of the patient’s age or expected length of life or
23 of the patient’s present or predicted disability, degree
24 of medical dependency, or quality of life.

1 “(d) *ELIGIBILITY CRITERIA.*—*To be eligible to receive*
2 *assistance under this section, an entity shall—*

3 “(1) *be a health care group;*

4 “(2) *meet quality standards established by the*
5 *Secretary, including—*

6 “(A) *the implementation of continuous*
7 *quality improvement mechanisms that are aimed*
8 *at integrating community-based support services,*
9 *primary care, and referral care;*

10 “(B) *the implementation of activities to in-*
11 *crease the delivery of effective care to bene-*
12 *ficiaries;*

13 “(C) *encouraging patient participation in*
14 *preference-based decisions;*

15 “(D) *the implementation of activities to en-*
16 *courage the coordination and integration of med-*
17 *ical service delivery; and*

18 “(E) *the implementation of activities to*
19 *measure and document the financial impact on*
20 *the health care marketplace of altering the incen-*
21 *tives of health care delivery and changing the al-*
22 *location of resources; and*

23 “(3) *meet such other requirements as the Sec-*
24 *retary may establish.*

1 “(e) *WAIVER AUTHORITY.*—*The Secretary may waive*
 2 *such requirements of titles XI and XVIII as may be nec-*
 3 *essary to carry out the purposes of the demonstration pro-*
 4 *gram established under this section.*

5 “(f) *BUDGET NEUTRALITY.*—*With respect to the 5-year*
 6 *period of the demonstration program under subsection (b),*
 7 *the aggregate expenditures under this title for such period*
 8 *shall not exceed the aggregate expenditures that would have*
 9 *been expended under this title if the program established*
 10 *under this section had not been implemented.*

11 “(g) *NOTICE REQUIREMENTS.*—*In the case of an indi-*
 12 *vidual that receives health care items or services under a*
 13 *demonstration program carried out under this section, the*
 14 *Secretary shall ensure that such individual is notified of*
 15 *any waivers of coverage or payment rules that are applica-*
 16 *ble to such individual under this title as a result of the*
 17 *participation of the individual in such program.*

18 “(h) *PARTICIPATION AND SUPPORT BY FEDERAL*
 19 *AGENCIES.*—*In carrying out the demonstration program*
 20 *under this section, the Secretary may direct—*

21 “(1) *the Director of the National Institutes of*
 22 *Health to expand the efforts of the Institutes to evalu-*
 23 *ate current medical technologies and improve the*
 24 *foundation for evidence-based practice;*

1 “(2) the Administrator of the Agency for
 2 Healthcare Research and Quality to, where possible
 3 and appropriate, use the program under this section
 4 as a laboratory for the study of quality improvement
 5 strategies and to evaluate, monitor, and disseminate
 6 information relevant to such program; and

7 “(3) the Administrator of the Centers for Medi-
 8 care & Medicaid Services and the Administrator of
 9 the Center for Medicare Choices to support linkages of
 10 relevant medicare data to registry information from
 11 participating health care groups for the beneficiary
 12 populations served by the participating groups, for
 13 analysis supporting the purposes of the demonstration
 14 program, consistent with the applicable provisions of
 15 the Health Insurance Portability and Accountability
 16 Act of 1996.

17 “(i) IMPLEMENTATION.—The Secretary shall not im-
 18 plement the demonstration program before October 1,
 19 2004.”.

20 **SEC. 442. MEDICARE COMPLEX CLINICAL CARE MANAGE-**
 21 **MENT PAYMENT DEMONSTRATION.**

22 (a) ESTABLISHMENT.—

23 (1) IN GENERAL.—The Secretary shall establish
 24 a demonstration program to make the medicare pro-
 25 gram more responsive to needs of eligible beneficiaries

1 *by promoting continuity of care, helping stabilize*
2 *medical conditions, preventing or minimizing acute*
3 *exacerbations of chronic conditions, and reducing ad-*
4 *verse health outcomes, such as adverse drug inter-*
5 *actions related to polypharmacy.*

6 (2) *SITES.*—*The Secretary shall designate 6 sites*
7 *at which to conduct the demonstration program under*
8 *this section, of which at least 3 shall be in an urban*
9 *area and at least 1 shall be in a rural area. One of*
10 *the sites shall be located in the State of Arkansas.*

11 (3) *DURATION.*—*The Secretary shall conduct the*
12 *demonstration program under this section for a 3-*
13 *year period.*

14 (4) *IMPLEMENTATION.*—*The Secretary shall not*
15 *implement the demonstration program before October*
16 *1, 2004.*

17 (b) *PARTICIPANTS.*—*Any eligible beneficiary who re-*
18 *sides in an area designated by the Secretary as a dem-*
19 *onstration site under subsection (a)(2) may participate in*
20 *the demonstration program under this section if such bene-*
21 *ficiary identifies a principal care physician who agrees to*
22 *manage the complex clinical care of the eligible beneficiary*
23 *under the demonstration program.*

24 (c) *PRINCIPAL CARE PHYSICIAN RESPONSIBILITIES.*—
25 *The Secretary shall enter into an agreement with each prin-*

1 *principal care physician who agrees to manage the complex*
2 *clinical care of an eligible beneficiary under subsection (b)*
3 *under which the principal care physician shall—*

4 (1) *serve as the primary contact of the eligible*
5 *beneficiary in accessing items and services for which*
6 *payment may be made under the medicare program;*

7 (2) *maintain medical information related to care*
8 *provided by other health care providers who provide*
9 *health care items and services to the eligible bene-*
10 *ficiary, including clinical reports, medication and*
11 *treatments prescribed by other physicians, hospital*
12 *and hospital outpatient services, skilled nursing home*
13 *care, home health care, and medical equipment serv-*
14 *ices;*

15 (3) *monitor and advocate for the continuity of*
16 *care of the eligible beneficiary and the use of evidence-*
17 *based guidelines;*

18 (4) *promote self-care and family caregiver in-*
19 *volvement where appropriate;*

20 (5) *have appropriate staffing arrangements to*
21 *conduct patient self-management and other care co-*
22 *ordination activities as specified by the Secretary;*

23 (6) *refer the eligible beneficiary to community*
24 *services organizations and coordinate the services of*

1 *such organizations with the care provided by health*
 2 *care providers; and*

3 *(7) meet such other complex care management*
 4 *requirements as the Secretary may specify.*

5 *(d) COMPLEX CLINICAL CARE MANAGEMENT FEE.—*

6 *(1) PAYMENT.—Under an agreement entered into*
 7 *under subsection (c), the Secretary shall pay to each*
 8 *principal care physician, on behalf of each eligible*
 9 *beneficiary under the care of that physician, the com-*
 10 *plex clinical care management fee developed by the*
 11 *Secretary under paragraph (2).*

12 *(2) DEVELOPMENT OF FEE.—The Secretary shall*
 13 *develop a complex care management fee under this*
 14 *paragraph that is paid on a monthly basis and which*
 15 *shall be payment in full for all the functions per-*
 16 *formed by the principal care physician under the*
 17 *demonstration program, including any functions per-*
 18 *formed by other qualified practitioners acting on be-*
 19 *half of the physician, appropriate staff under the su-*
 20 *pervision of the physician, and any other person*
 21 *under a contract with the physician, including any*
 22 *person who conducts patient self-management and*
 23 *caregiver education under subsection (c)(4).*

24 *(e) FUNDING.—*

1 (1) *IN GENERAL.*—*The Secretary shall provide*
 2 *for the transfer from the Federal Supplementary In-*
 3 *surance Trust Fund established under section 1841 of*
 4 *the Social Security Act (42 U.S.C. 1395t) of such*
 5 *funds as are necessary for the costs of carrying out*
 6 *the demonstration program under this section.*

7 (2) *BUDGET NEUTRALITY.*—*In conducting the*
 8 *demonstration program under this section, the Sec-*
 9 *retary shall ensure that the aggregate payments made*
 10 *by the Secretary do not exceed the amount which the*
 11 *Secretary would have paid if the demonstration pro-*
 12 *gram under this section was not implemented.*

13 (f) *WAIVER AUTHORITY.*—*The Secretary may waive*
 14 *such requirements of titles XI and XVIII of the Social Secu-*
 15 *rity Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be*
 16 *necessary for the purpose of carrying out the demonstration*
 17 *program under this section.*

18 (g) *REPORT.*—*Not later than 6 months after the com-*
 19 *pletion of the demonstration program under this section,*
 20 *the Secretary shall submit to Congress a report on such pro-*
 21 *gram, together with recommendations for such legislation*
 22 *and administrative action as the Secretary determines to*
 23 *be appropriate.*

24 (h) *DEFINITIONS.*—*In this section:*

1 (1) *ACTIVITY OF DAILY LIVING.*—The term “ac-
 2 tivity of daily living” means eating, toiling, transfer-
 3 ring, bathing, dressing, and continence.

4 (2) *CHRONIC CONDITION.*—The term “chronic
 5 condition” means a biological, physical, or mental
 6 condition that is likely to last a year or more, for
 7 which there is no known cure, for which there is a
 8 need for ongoing medical care, and which may affect
 9 an individual’s ability to carry out activities of daily
 10 living or instrumental activities of daily living, or
 11 both.

12 (3) *ELIGIBLE BENEFICIARY.*—The term “eligible
 13 beneficiary” means any individual who—

14 (A) is enrolled for benefits under part B of
 15 the medicare program;

16 (B) has at least 4 complex medical condi-
 17 tions (one of which may be cognitive impair-
 18 ment); and

19 (C) has—

20 (i) an inability to self-manage their
 21 care; or

22 (ii) a functional limitation defined as
 23 an impairment in 1 or more activity of
 24 daily living or instrumental activity of
 25 daily living.

1 (4) *INSTRUMENTAL ACTIVITY OF DAILY LIVING.*—
 2 *The term “instrumental activity of daily living”*
 3 *means meal preparation, shopping, housekeeping,*
 4 *laundry, money management, telephone use, and*
 5 *transportation use.*

6 (5) *MEDICARE PROGRAM.*—*The term “medicare*
 7 *program” means the health care program under title*
 8 *XVIII of the Social Security Act (42 U.S.C. 1395 et*
 9 *seq.).*

10 (6) *PRINCIPAL CARE PHYSICIAN.*—*The term*
 11 *“principal care physician” means the physician with*
 12 *primary responsibility for overall coordination of the*
 13 *care of an eligible beneficiary (as specified in a writ-*
 14 *ten plan of care) who may be a primary care physi-*
 15 *cian or a specialist.*

16 **SEC. 443. MEDICARE FEE-FOR-SERVICE CARE COORDINA-**
 17 **TION DEMONSTRATION PROGRAM.**

18 (a) *ESTABLISHMENT.*—

19 (1) *IN GENERAL.*—*The Secretary shall establish*
 20 *a demonstration program to contract with qualified*
 21 *care management organizations to provide health risk*
 22 *assessment and care management services to eligible*
 23 *beneficiaries who receive care under the original*
 24 *medicare fee-for-service program under parts A and B*

1 of title XVIII of the Social Security Act to eligible
2 beneficiaries.

3 (2) *SITES.*—*The Secretary shall designate 6 sites*
4 *at which to conduct the demonstration program under*
5 *this section. In selecting sites under this paragraph,*
6 *the Secretary shall give preference to sites located in*
7 *rural areas.*

8 (3) *DURATION.*—*The Secretary shall conduct the*
9 *demonstration program under this section for a 5-*
10 *year period.*

11 (4) *IMPLEMENTATION.*—*The Secretary shall not*
12 *implement the demonstration program before October*
13 *1, 2004.*

14 (b) *PARTICIPANTS.*—*Any eligible beneficiary who re-*
15 *sides in an area designated by the Secretary as a dem-*
16 *onstration site under subsection (a)(2) may participate in*
17 *the demonstration program under this section if such bene-*
18 *ficiary identifies a care management organization who*
19 *agrees to furnish care management services to the eligible*
20 *beneficiary under the demonstration program.*

21 (c) *CONTRACTS WITH CMOS.*—

22 (1) *IN GENERAL.*—*The Secretary shall enter into*
23 *a contract with care management organizations to*
24 *provide care management services to eligible bene-*

1 *ficiaries residing in the area served by the care man-*
 2 *agement organization.*

3 (2) *CANCELLATION.—The Secretary may cancel*
 4 *a contract entered into under paragraph (1) if the*
 5 *care management organization does not meet nego-*
 6 *tiated savings or quality outcomes targets for the*
 7 *year.*

8 (3) *NUMBER OF CMOS.—The Secretary may con-*
 9 *tract with more than 1 care management organiza-*
 10 *tion in a geographic area.*

11 (d) *PAYMENT TO CMOS.—*

12 (1) *PAYMENT.—Under an contract entered into*
 13 *under subsection (c), the Secretary shall pay care*
 14 *management organizations a fee for which the care*
 15 *management organization is partially at risk based*
 16 *on bids submitted by care management organizations.*

17 (2) *PORTION OF PAYMENT AT RISK.—The Sec-*
 18 *retary shall establish a benchmark for quality and*
 19 *cost against which the results of the care management*
 20 *organization are to be measured. The Secretary may*
 21 *not pay a care management organization the portion*
 22 *of the fee described in paragraph (1) that is at risk*
 23 *unless the Secretary determines that the care manage-*
 24 *ment organization has met the agreed upon savings*
 25 *and outcomes targets for the year.*

1 (e) *FUNDING.*—

2 (1) *IN GENERAL.*—*The Secretary shall provide*
 3 *for the transfer from the Federal Hospital Insurance*
 4 *Trust Fund under section 1817 of the Social Security*
 5 *Act (42 U.S.C. 1395i) and the Federal Supple-*
 6 *mentary Insurance Trust Fund established under sec-*
 7 *tion 1841 of such Act (42 U.S.C. 1395t), in such pro-*
 8 *portion as the Secretary determines to be appropriate,*
 9 *of such funds as are necessary for the costs of car-*
 10 *rying out the demonstration program under this sec-*
 11 *tion.*

12 (2) *BUDGET NEUTRALITY.*—*In conducting the*
 13 *demonstration program under this section, the Sec-*
 14 *retary shall ensure that the aggregate payments made*
 15 *by the Secretary do not exceed the amount which the*
 16 *Secretary would have paid if the demonstration pro-*
 17 *gram under this section was not implemented.*

18 (f) *WAIVER AUTHORITY.*—

19 (1) *IN GENERAL.*—*The Secretary may waive*
 20 *such requirements of titles XI and XVIII of the Social*
 21 *Security Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as*
 22 *may be necessary for the purpose of carrying out the*
 23 *demonstration program under this section.*

24 (2) *WAIVER OF MEDIGAP PREEMPTIONS.*—*The*
 25 *Secretary shall waive any provision of section 1882*

1 of the Social Security Act that would prevent an in-
 2 surance carrier described in subsection (h)(3)(D) from
 3 participating in the demonstration program under
 4 this section.

5 (g) *REPORT*.—Not later than 6 months after the com-
 6 pletion of the demonstration program under this section,
 7 the Secretary shall submit to Congress a report on such pro-
 8 gram, together with recommendations for such legislation
 9 and administrative action as the Secretary determines to
 10 be appropriate.

11 (h) *DEFINITIONS*.—In this section:

12 (1) *CARE MANAGEMENT SERVICES*.—The term
 13 “care management services” means services that are
 14 furnished to an eligible beneficiary (as defined in
 15 paragraph (2)) by a care management organization
 16 (as defined in paragraph (3)) in accordance with
 17 guidelines established by the Secretary that are con-
 18 sistent with guidelines established by the American
 19 Geriatrics Society.

20 (2) *ELIGIBLE BENEFICIARY*.—The term “eligible
 21 beneficiary” means an individual who is—

22 (A) entitled to (or enrolled for) benefits
 23 under part A and enrolled for benefits under
 24 part B of the Social Security Act (42 U.S.C.
 25 1395c et seq.; 1395j et seq.);

1 (B) not enrolled with a Medicare+Choice
 2 plan or a MedicareAdvantage plan under part
 3 C; and

4 (C) at high-risk (as defined by the Sec-
 5 retary, but including eligible beneficiaries with
 6 multiple sclerosis or another disabling chronic
 7 condition, eligible beneficiaries residing in a
 8 nursing home or at risk for nursing home place-
 9 ment, or eligible beneficiaries eligible for assist-
 10 ance under a State plan under title XIX).

11 (3) CARE MANAGEMENT ORGANIZATION.—The
 12 term “care management organization” means an or-
 13 ganization that meets such qualifications as the Sec-
 14 retary may specify and includes any of the following:

15 (A) A physician group practice, hospital,
 16 home health agency, or hospice program.

17 (B) A disease management organization.

18 (C) A Medicare+Choice or
 19 MedicareAdvantage organization.

20 (D) Insurance carriers offering medicare
 21 supplemental policies under section 1882 of the
 22 Social Security Act (42 U.S.C. 1395ss).

23 (E) Such other entity as the Secretary de-
 24 termines to be appropriate.

1 **SEC. 444. GAO STUDY OF GEOGRAPHIC DIFFERENCES IN**
2 **PAYMENTS FOR PHYSICIANS' SERVICES.**

3 (a) *STUDY.*—*The Comptroller General of the United*
4 *States shall conduct a study of differences in payment*
5 *amounts under the physician fee schedule under section*
6 *1848 of the Social Security Act (42 U.S.C. 1395w–4) for*
7 *physicians' services in different geographic areas. Such*
8 *study shall include—*

9 (1) *an assessment of the validity of the geo-*
10 *graphic adjustment factors used for each component of*
11 *the fee schedule;*

12 (2) *an evaluation of the measures used for such*
13 *adjustment, including the frequency of revisions;*

14 (3) *an evaluation of the methods used to deter-*
15 *mine professional liability insurance costs used in*
16 *computing the malpractice component, including a*
17 *review of increases in professional liability insurance*
18 *premiums and variation in such increases by State*
19 *and physician specialty and methods used to update*
20 *the geographic cost of practice index and relative*
21 *weights for the malpractice component;*

22 (4) *an evaluation of whether there is a sound*
23 *economic basis for the implementation of the adjust-*
24 *ment under subparagraphs (E) and (F) of section*
25 *1848(e)(1) of the Social Security Act (42 U.S.C.*

1 1395w-4(e)(1)), as added by section 421, in those
2 areas in which the adjustment applies;

3 (5) an evaluation of the effect of such adjustment
4 on physician location and retention in areas affected
5 by such adjustment, taking into account—

6 (A) differences in recruitment costs and re-
7 tention rates for physicians, including special-
8 ists, between large urban areas and other areas;
9 and

10 (B) the mobility of physicians, including
11 specialists, over the last decade;

12 (6) an evaluation of the appropriateness of ex-
13 tending such adjustment or making such adjustment
14 permanent;

15 (7) an evaluation of the adjustment of the work
16 geographic practice cost index required under section
17 1848(e)(1)(A)(iii) of the Social Security Act (42
18 U.S.C. 1395w-4(e)(1)(A)(iii)) to reflect $\frac{1}{4}$ of the area
19 cost difference in physician work;

20 (8) an evaluation of the effect of the adjustment
21 described in paragraph (7) on physician location and
22 retention in higher than average cost-of-living areas,
23 taking into account difference in recruitment costs
24 and retention rates for physicians, including special-
25 ists; and

1 (9) *an evaluation of the appropriateness of the*
 2 *1/4 adjustment for the work geographic practice cost*
 3 *index.”.*

4 (b) *REPORT.*—*Not later than 1 year after the date of*
 5 *enactment of this Act, the Comptroller General of the United*
 6 *States shall submit to Congress a report on the study con-*
 7 *ducted under subsection (a). The report shall include rec-*
 8 *ommendations regarding the use of more current data in*
 9 *computing geographic cost of practice indices as well as the*
 10 *use of data directly representative of physicians’ costs (rath-*
 11 *er than proxy measures of such costs).*

12 **SEC. 445. IMPROVED PAYMENT FOR CERTAIN MAMMOG-**
 13 **RAPHY SERVICES.**

14 (a) *EXCLUSION FROM OPD FEE SCHEDULE.*—*Section*
 15 *1833(t)(1)(B)(iv) (42 U.S.C. 13951(t)(1)(B)(iv)) is amend-*
 16 *ed by inserting before the period at the end the following:*
 17 *“and does not include screening mammography (as defined*
 18 *in section 1861(jj)) and unilateral and bilateral diagnostic*
 19 *mammography”.*

20 (b) *EFFECTIVE DATE.*—*The amendment made by sub-*
 21 *section (a) shall apply to mammography performed on or*
 22 *after January 1, 2005.*

1 **SEC. 446. IMPROVEMENT OF OUTPATIENT VISION SERVICES**

2 **UNDER PART B.**

3 (a) *COVERAGE UNDER PART B.*—Section 1861(s)(2)
4 (42 U.S.C. 1395x(s)(2)) is amended—

5 (1) in subparagraph (U), by striking “and” after
6 the semicolon at the end;

7 (2) in subparagraph (V)(iii), by adding “and”
8 after the semicolon at the end; and

9 (3) by adding at the end the following new sub-
10 paragraph:

11 “(W) vision rehabilitation services (as defined in
12 subsection (ww)(1));”.

13 (b) *SERVICES DESCRIBED.*—Section 1861 (42 U.S.C.
14 1395x) is amended by adding at the end the following new
15 subsection:

16 “Vision Rehabilitation Services; Vision Rehabilitation
17 Professional

18 “(ww)(1)(A) The term ‘vision rehabilitation services’
19 means rehabilitative services (as determined by the Sec-
20 retary in regulations) furnished—

21 “(i) to an individual diagnosed with a vision
22 impairment (as defined in paragraph (6));

23 “(ii) pursuant to a plan of care established by
24 a qualified physician (as defined in subparagraph
25 (C)) or by a qualified occupational therapist that is
26 periodically reviewed by a qualified physician;

1 “(iii) in an appropriate setting (including the
2 home of the individual receiving such services if speci-
3 fied in the plan of care); and

4 “(iv) by any of the following individuals:

5 “(I) A qualified physician.

6 “(II) A qualified occupational therapist.

7 “(III) A vision rehabilitation professional
8 (as defined in paragraph (2)) while under the
9 general supervision (as defined in subparagraph
10 (D)) of a qualified physician.

11 “(B) In the case of vision rehabilitation services fur-
12 nished by a vision rehabilitation professional, the plan of
13 care may only be established and reviewed by a qualified
14 physician.

15 “(C) The term ‘qualified physician’ means—

16 “(i) a physician (as defined in subsection (r)(1))
17 who is an ophthalmologist; or

18 “(ii) a physician (as defined in subsection (r)(4)
19 (relating to a doctor of optometry)).

20 “(D) The term ‘general supervision’ means, with re-
21 spect to a vision rehabilitation professional, overall direc-
22 tion and control of that professional by the qualified physi-
23 cian who established the plan of care for the individual,
24 but the presence of the qualified physician is not required

1 *during the furnishing of vision rehabilitation services by*
 2 *that professional to the individual.*

3 “(2) *The term ‘vision rehabilitation professional’*
 4 *means any of the following individuals:*

5 “(A) *An orientation and mobility specialist (as*
 6 *defined in paragraph (3)).*

7 “(B) *A rehabilitation teacher (as defined in*
 8 *paragraph (4)).*

9 “(C) *A low vision therapist (as defined in para-*
 10 *graph (5)).*

11 “(3) *The term ‘orientation and mobility specialist’*
 12 *means an individual who—*

13 “(A) *if a State requires licensure or certification*
 14 *of orientation and mobility specialists, is licensed or*
 15 *certified by that State as an orientation and mobility*
 16 *specialist;*

17 “(B)(i) *holds a baccalaureate or higher degree*
 18 *from an accredited college or university in the United*
 19 *States (or an equivalent foreign degree) with a con-*
 20 *centration in orientation and mobility; and*

21 “(ii) *has successfully completed 350 hours of*
 22 *clinical practicum under the supervision of an ori-*
 23 *entation and mobility specialist and has furnished*
 24 *not less than 9 months of supervised full-time orienta-*
 25 *tion and mobility services;*

1 “(C) has successfully completed the national ex-
 2 amination in orientation and mobility administered
 3 by the Academy for Certification of Vision Rehabilita-
 4 tion and Education Professionals; and

5 “(D) meets such other criteria as the Secretary
 6 establishes.

7 “(4) The term ‘rehabilitation teacher’ means an indi-
 8 vidual who—

9 “(A) if a State requires licensure or certification
 10 of rehabilitation teachers, is licensed or certified by
 11 the State as a rehabilitation teacher;

12 “(B)(i) holds a baccalaureate or higher degree
 13 from an accredited college or university in the United
 14 States (or an equivalent foreign degree) with a con-
 15 centration in rehabilitation teaching, or holds such a
 16 degree in a health field; and

17 “(ii) has successfully completed 350 hours of
 18 clinical practicum under the supervision of a reha-
 19 bilitation teacher and has furnished not less than 9
 20 months of supervised full-time rehabilitation teaching
 21 services;

22 “(C) has successfully completed the national ex-
 23 amination in rehabilitation teaching administered by
 24 the Academy for Certification of Vision Rehabilita-
 25 tion and Education Professionals; and

1 “(D) meets such other criteria as the Secretary
2 establishes.

3 “(5) The term ‘low vision therapist’ means an indi-
4 vidual who—

5 “(A) if a State requires licensure or certification
6 of low vision therapists, is licensed or certified by the
7 State as a low vision therapist;

8 “(B)(i) holds a baccalaureate or higher degree
9 from an accredited college or university in the United
10 States (or an equivalent foreign degree) with a con-
11 centration in low vision therapy, or holds such a de-
12 gree in a health field; and

13 “(ii) has successfully completed 350 hours of
14 clinical practicum under the supervision of a physi-
15 cian, and has furnished not less than 9 months of su-
16 pervised full-time low vision therapy services;

17 “(C) has successfully completed the national ex-
18 amination in low vision therapy administered by the
19 Academy for Certification of Vision Rehabilitation
20 and Education Professionals; and

21 “(D) meets such other criteria as the Secretary
22 establishes.

23 “(6) The term ‘vision impairment’ means vision loss
24 that constitutes a significant limitation of visual capability
25 resulting from disease, trauma, or a congenital or degenera-

1 *tive condition that cannot be corrected by conventional*
 2 *means, including refractive correction, medication, or sur-*
 3 *gery, and that is manifested by 1 or more of the following:*

4 “(A) *Best corrected visual acuity of less than 20/*
 5 *60, or significant central field defect.*”

6 “(B) *Significant peripheral field defect including*
 7 *homonymous or heteronymous bilateral visual field*
 8 *defect or generalized contraction or constriction of*
 9 *field.*”

10 “(C) *Reduced peak contrast sensitivity in con-*
 11 *junction with a condition described in subparagraph*
 12 *(A) or (B).*”

13 “(D) *Such other diagnoses, indications, or other*
 14 *manifestations as the Secretary may determine to be*
 15 *appropriate.*”

16 *(c) PAYMENT UNDER PART B.—*

17 (1) *PHYSICIAN FEE SCHEDULE.—Section*
 18 *1848(j)(3) (42 U.S.C. 1395w-4(j)(3)) is amended by*
 19 *inserting “(2)(W),” after “(2)(S).”*

20 (2) *CARVE OUT FROM HOSPITAL OUTPATIENT*
 21 *DEPARTMENT PROSPECTIVE PAYMENT SYSTEM.—Sec-*
 22 *tion 1833(t)(1)(B)(iv) (42 U.S.C. 1395l(t)(1)(B)(iv))*
 23 *is amended by inserting “vision rehabilitation serv-*
 24 *ices (as defined in section 1861(ww)(1)) or” after*
 25 *“does not include”.*

(3) CLARIFICATION OF BILLING REQUIREMENTS.—*The first sentence of section 1842(b)(6) of such Act (42 U.S.C. 1395u(b)(6)) is amended—*

(A) by striking “and” before “(G)”; and

(B) by inserting before the period the following: “, and (H) in the case of vision rehabilitation services (as defined in section 1861(ww)(1)) furnished by a vision rehabilitation professional (as defined in section 1861(ww)(2)) while under the general supervision (as defined in section 1861(ww)(1)(D)) of a qualified physician (as defined in section 1861(ww)(1)(C)), payment shall be made to (i) the qualified physician or (ii) the facility (such as a rehabilitation agency, a clinic, or other facility) through which such services are furnished under the plan of care if there is a contractual arrangement between the vision rehabilitation professional and the facility under which the facility submits the bill for such services”.

(d) PLAN OF CARE.—*Section 1835(a)(2) (42 U.S.C. 1395n(a)(2)) is amended—*

(1) in subparagraph (E), by striking “and” after the semicolon at the end;

1 (2) in subparagraph (F), by striking the period
2 at the end and inserting “; and”; and

3 (3) by inserting after subparagraph (F) the fol-
4 lowing new subparagraph:

5 “(G) in the case of vision rehabilitation
6 services, (i) such services are or were required be-
7 cause the individual needed vision rehabilitation
8 services, (ii) an individualized, written plan for
9 furnishing such services has been established (I)
10 by a qualified physician (as defined in section
11 1861(ww)(1)(C)), (II) by a qualified occupa-
12 tional therapist, or (III) in the case of such serv-
13 ices furnished by a vision rehabilitation profes-
14 sional, by a qualified physician, (iii) the plan is
15 periodically reviewed by the qualified physician,
16 and (iv) such services are or were furnished
17 while the individual is or was under the care of
18 the qualified physician.”.

19 (e) *RELATIONSHIP TO REHABILITATION ACT OF*
20 1973.—*The provision of vision rehabilitation services under*
21 *the medicare program under title XVIII (42 U.S.C. 1395*
22 *et seq.) shall not be taken into account for any purpose*
23 *under the Rehabilitation Act of 1973 (29 U.S.C. 701 et*
24 *seq.).*

25 (f) *EFFECTIVE DATE.*—

1 (1) *INTERIM, FINAL REGULATIONS.*—*The Sec-*
 2 *retary shall publish a rule under this section in the*
 3 *Federal Register by not later than 180 days after the*
 4 *date of enactment of this Act to carry out the provi-*
 5 *sions of this section. Such rule shall be effective and*
 6 *final immediately on an interim basis, but is subject*
 7 *to change and revision after public notice and oppor-*
 8 *tunity for a period for public comment of not less*
 9 *than 60 days.*

10 (2) *CONSULTATION.*—*The Secretary shall consult*
 11 *with the National Vision Rehabilitation Cooperative,*
 12 *the Association for Education and Rehabilitation of*
 13 *the Blind and Visually Impaired, the Academy for*
 14 *Certification of Vision Rehabilitation and Education*
 15 *Professionals, the American Academy of Ophthal-*
 16 *mology, the American Occupational Therapy Associa-*
 17 *tion, the American Optometric Association, and such*
 18 *other qualified professional and consumer organiza-*
 19 *tions as the Secretary determines appropriate in pro-*
 20 *mulgating regulations to carry out this section.*

21 **SEC. 447. GAO STUDY AND REPORT ON THE PROPAGATION**
 22 **OF CONCIERGE CARE.**

23 (a) *STUDY.*—

24 (1) *IN GENERAL.*—*The Comptroller General of*
 25 *the United States shall conduct a study on concierge*

1 *care (as defined in paragraph (2)) to determine the*
 2 *extent to which such care—*

3 *(A) is used by medicare beneficiaries (as de-*
 4 *finied in section 1802(b)(5)(A) of the Social Secu-*
 5 *rity Act (42 U.S.C. 1395a(b)(5)(A))); and*

6 *(B) has impacted upon the access of medi-*
 7 *care beneficiaries (as so defined) to items and*
 8 *services for which reimbursement is provided*
 9 *under the medicare program under title XVIII of*
 10 *the Social Security Act (42 U.S.C. 1395 et seq.).*

11 *(2) CONCIERGE CARE.—In this section, the term*
 12 *“conciierge care” means an arrangement under which,*
 13 *as a prerequisite for the provision of a health care*
 14 *item or service to an individual, a physician, practi-*
 15 *tioner (as described in section 1842(b)(18)(C) of the*
 16 *Social Security Act (42 U.S.C. 1395u(b)(18)(C))), or*
 17 *other individual—*

18 *(A) charges a membership fee or another in-*
 19 *cidental fee to an individual desiring to receive*
 20 *the health care item or service from such physi-*
 21 *cian, practitioner, or other individual; or*

22 *(B) requires the individual desiring to re-*
 23 *ceive the health care item or service from such*
 24 *physician, practitioner, or other individual to*
 25 *purchase an item or service.*

1 (b) *REPORT*.—Not later than the date that is 12
 2 months after the date of enactment of this Act, the Comp-
 3 troller General of the United States shall submit to Congress
 4 a report on the study conducted under subsection (a)(1) to-
 5 gether with such recommendations for legislative or admin-
 6 istrative action as the Comptroller General determines to
 7 be appropriate.

8 **SEC. 448. COVERAGE OF MARRIAGE AND FAMILY THERA-**
 9 **PIST SERVICES AND MENTAL HEALTH COUN-**
 10 **SELOR SERVICES UNDER PART B OF THE**
 11 **MEDICARE PROGRAM.**

12 (a) *COVERAGE OF SERVICES*.—

13 (1) *IN GENERAL*.—Section 1861(s)(2) (42 U.S.C.
 14 1395x(s)(2)) is amended—

15 (A) in subparagraph (U), by striking “and”
 16 after the semicolon at the end;

17 (B) in subparagraph (V)(iii), by inserting
 18 “and” after the semicolon at the end; and

19 (C) by adding at the end the following new
 20 subparagraph:

21 “(W) marriage and family therapist services (as
 22 defined in subsection (ww)(1)) and mental health
 23 counselor services (as defined in subsection
 24 (ww)(3));”.

1 (2) *DEFINITIONS.*—Section 1861 (42 U.S.C.
2 1395x) is amended by adding at the end the following
3 new subsection:

4 “*Marriage and Family Therapist Services; Marriage and*
5 *Family Therapist; Mental Health Counselor Services;*
6 *Mental Health Counselor*

7 “(ww)(1) *The term ‘marriage and family therapist*
8 *services’ means services performed by a marriage and fam-*
9 *ily therapist (as defined in paragraph (2)) for the diagnosis*
10 *and treatment of mental illnesses, which the marriage and*
11 *family therapist is legally authorized to perform under*
12 *State law (or the State regulatory mechanism provided by*
13 *State law) of the State in which such services are performed,*
14 *as would otherwise be covered if furnished by a physician*
15 *or as an incident to a physician’s professional service, but*
16 *only if no facility or other provider charges or is paid any*
17 *amounts with respect to the furnishing of such services.*

18 “(2) *The term ‘marriage and family therapist’ means*
19 *an individual who—*

20 “(A) *possesses a master’s or doctoral degree*
21 *which qualifies for licensure or certification as a mar-*
22 *riage and family therapist pursuant to State law;*

23 “(B) *after obtaining such degree has performed*
24 *at least 2 years of clinical supervised experience in*
25 *marriage and family therapy; and*

1 “(C) in the case of an individual performing
 2 services in a State that provides for licensure or cer-
 3 tification of marriage and family therapists, is li-
 4 censed or certified as a marriage and family therapist
 5 in such State.

6 “(3) The term ‘mental health counselor services’ means
 7 services performed by a mental health counselor (as defined
 8 in paragraph (4)) for the diagnosis and treatment of mental
 9 illnesses which the mental health counselor is legally author-
 10 ized to perform under State law (or the State regulatory
 11 mechanism provided by the State law) of the State in which
 12 such services are performed, as would otherwise be covered
 13 if furnished by a physician or as incident to a physician’s
 14 professional service, but only if no facility or other provider
 15 charges or is paid any amounts with respect to the fur-
 16 nishing of such services.

17 “(4) The term ‘mental health counselor’ means an in-
 18 dividual who—

19 “(A) possesses a master’s or doctor’s degree in
 20 mental health counseling or a related field;

21 “(B) after obtaining such a degree has performed
 22 at least 2 years of supervised mental health counselor
 23 practice; and

24 “(C) in the case of an individual performing
 25 services in a State that provides for licensure or cer-

1 *tification of mental health counselors or professional*
 2 *counselors, is licensed or certified as a mental health*
 3 *counselor or professional counselor in such State.”.*

4 (3) *PROVISION FOR PAYMENT UNDER PART B.—*
 5 *Section 1832(a)(2)(B) (42 U.S.C. 1395k(a)(2)(B)) is*
 6 *amended by adding at the end the following new*
 7 *clause:*

8 “(v) *marriage and family therapist*
 9 *services and mental health counselor serv-*
 10 *ices;”.*

11 (4) *AMOUNT OF PAYMENT.—Section 1833(a)(1)*
 12 *(42 U.S.C. 1395l(a)(1)) is amended—*

13 (A) *by striking “and (U)” and inserting*
 14 *“(U)”;* *and*

15 (B) *by inserting before the semicolon at the*
 16 *end the following: “, and (V) with respect to*
 17 *marriage and family therapist services and men-*
 18 *tal health counselor services under section*
 19 *1861(s)(2)(W), the amounts paid shall be 80 per-*
 20 *cent of the lesser of the actual charge for the serv-*
 21 *ices or 75 percent of the amount determined for*
 22 *payment of a psychologist under subparagraph*
 23 *(L)”.*

24 (5) *EXCLUSION OF MARRIAGE AND FAMILY THER-*
 25 *APIST SERVICES AND MENTAL HEALTH COUNSELOR*

1 *SERVICES FROM SKILLED NURSING FACILITY PRO-*
 2 *SPECTIVE PAYMENT SYSTEM.*—*Section*
 3 *1888(e)(2)(A)(ii) (42 U.S.C. 1395yy(e)(2)(A)(ii)), as*
 4 *amended in section 301(a), is amended by inserting*
 5 *“marriage and family therapist services (as defined*
 6 *in subsection (ww)(1)), mental health counselor serv-*
 7 *ices (as defined in section 1861(ww)(3)),” after*
 8 *“qualified psychologist services,”.*

9 *(6) INCLUSION OF MARRIAGE AND FAMILY*
 10 *THERAPISTS AND MENTAL HEALTH COUNSELORS AS*
 11 *PRACTITIONERS FOR ASSIGNMENT OF CLAIMS.*—*Sec-*
 12 *tion 1842(b)(18)(C) (42 U.S.C. 1395u(b)(18)(C)) is*
 13 *amended by adding at the end the following new*
 14 *clauses:*

15 *“(vii) A marriage and family therapist (as de-*
 16 *fined in section 1861(ww)(2)).*

17 *“(viii) A mental health counselor (as defined in*
 18 *section 1861(ww)(4)).”.*

19 *(b) COVERAGE OF CERTAIN MENTAL HEALTH SERV-*
 20 *ICES PROVIDED IN CERTAIN SETTINGS.—*

21 *(1) RURAL HEALTH CLINICS AND FEDERALLY*
 22 *QUALIFIED HEALTH CENTERS.*—*Section*
 23 *1861(aa)(1)(B) (42 U.S.C. 1395x(aa)(1)(B)) is*
 24 *amended by striking “or by a clinical social worker*
 25 *(as defined in subsection (hh)(1)),” and inserting “,*

1 *by a clinical social worker (as defined in subsection*
 2 *(hh)(1)), by a marriage and family therapist (as de-*
 3 *defined in subsection (ww)(2)), or by a mental health*
 4 *counselor (as defined in subsection (ww)(4)),”.*

5 (2) *HOSPICE PROGRAMS.—Section*
 6 *1861(dd)(2)(B)(i)(III) (42 U.S.C.*
 7 *1395x(dd)(2)(B)(i)(III)) is amended by inserting “or*
 8 *a marriage and family therapist (as defined in sub-*
 9 *section (ww)(2))” after “social worker”.*

10 (c) *AUTHORIZATION OF MARRIAGE AND FAMILY*
 11 *THERAPISTS TO DEVELOP DISCHARGE PLANS FOR POST-*
 12 *HOSPITAL SERVICES.—Section 1861(ee)(2)(G) (42 U.S.C.*
 13 *1395x(ee)(2)(G)) is amended by inserting “marriage and*
 14 *family therapist (as defined in subsection (ww)(2)),” after*
 15 *“social worker,”.*

16 (d) *EFFECTIVE DATE.—The amendments made by this*
 17 *section shall apply with respect to services furnished on or*
 18 *after January 1, 2004.*

19 **SEC. 449. MEDICARE DEMONSTRATION PROJECT FOR DI-**
 20 **RECT ACCESS TO PHYSICAL THERAPY SERV-**
 21 **ICES.**

22 (a) *IN GENERAL.—The Secretary shall conduct a dem-*
 23 *onstration project under this section (in this section referred*
 24 *to as the “project”) to demonstrate the impact of allowing*
 25 *medicare fee-for-service beneficiaries direct access to out-*

1 *patient physical therapy services and physical therapy*
 2 *services furnished as comprehensive rehabilitation facility*
 3 *services on—*

4 *(1) costs under the medicare program under title*
 5 *XVIII of the Social Security Act; and*

6 *(2) the satisfaction of beneficiaries receiving such*
 7 *services.*

8 *(b) DEADLINE FOR ESTABLISHMENT; DURATION;*
 9 *SITES.—*

10 *(1) DEADLINE.—The Secretary shall establish the*
 11 *project not later than 1 year after the date of enact-*
 12 *ment of this Act.*

13 *(2) DURATION; SITES.—The project shall—*

14 *(A) be conducted for a period of 3 years;*

15 *(B) include sites in at least 5 States; and*

16 *(C) to the extent feasible, be conducted on a*
 17 *statewide basis in each State included under sub-*
 18 *paragraph (B).*

19 *(3) EARLY TERMINATION.—Notwithstanding*
 20 *paragraph (2)(A), the Secretary may terminate the*
 21 *operation of the project at a site before the end of the*
 22 *3-year period specified in such paragraph if the Sec-*
 23 *retary determines, based on actual data, that the total*
 24 *amount expended for all services under this title for*
 25 *individuals at such site for a 12-month period are*

1 *greater than the total amount that would have been*
 2 *expended for such services for such individuals for*
 3 *such period but for the operation of the project at*
 4 *such site.*

5 *(c) WAIVER OF MEDICARE REQUIREMENTS.—The Sec-*
 6 *retary shall waive compliance with such requirements of the*
 7 *medicare program under title XVIII of the Social Security*
 8 *Act to the extent and for the period the Secretary finds nec-*
 9 *essary to conduct the demonstration project.*

10 *(d) EVALUATIONS AND REPORTS.—*

11 *(1) EVALUATIONS.—*

12 *(A) IN GENERAL.—The Secretary shall con-*
 13 *duct interim and final evaluations of the project.*

14 *(B) FOCUS.—The evaluations conducted*
 15 *under paragraph (1) shall—*

16 *(i) focus on the impact of the project*
 17 *on program costs under title XVIII of the*
 18 *Social Security Act and patient satisfaction*
 19 *with health care items and services for*
 20 *which payment is made under such title;*
 21 *and*

22 *(ii) include comparisons, with respect*
 23 *to episodes of care involving direct access to*
 24 *physical therapy services and episodes of*

1 care involving a physician referral for such
2 services, of—

3 (I) the average number of claims
4 paid per episode for outpatient phys-
5 ical therapy services and physical ther-
6 apy services furnished as comprehen-
7 sive outpatient rehabilitation facility
8 services;

9 (II) the average number of physi-
10 cian office visits per episode; and

11 (III) the average expenditures
12 under such title per episode.

13 (2) *INTERIM AND FINAL REPORTS.*—The Sec-
14 retary shall submit to the Committee on Finance of
15 the Senate and the Committees on Ways and Means
16 and Energy and Commerce of the House of Represent-
17 atives reports on the evaluations conducted under
18 paragraph (1) by—

19 (A) in the case of the report on the interim
20 evaluation, not later than the end of the second
21 year the project has been in operation; and

22 (B) in the case of the report on the final
23 evaluation, not later than 180 days after the
24 closing date of the project.

1 (3) *FUNDING FOR EVALUATION.*—*There are au-*
 2 *thorized to be appropriated such sums as may be nec-*
 3 *essary to provide for the evaluations and reports re-*
 4 *quired by this subsection.*

5 (e) *DEFINITIONS.*—*In this section:*

6 (1) *COMPREHENSIVE OUTPATIENT REHABILITA-*
 7 *TION SERVICES.*—*Subject to paragraph (2), the term*
 8 *“comprehensive outpatient rehabilitation services” has*
 9 *the meaning given to such term in section 1861(cc) of*
 10 *the Social Security Act (42 U.S.C. 1395x(cc)).*

11 (2) *DIRECT ACCESS.*—*The term “direct access”*
 12 *means, with respect to outpatient physical therapy*
 13 *services and physical therapy services furnished as*
 14 *comprehensive outpatient rehabilitation facility serv-*
 15 *ices, coverage of and payment for such services in ac-*
 16 *cordance with the provisions of title XVIII of the So-*
 17 *cial Security Act, except that sections 1835(a)(2),*
 18 *1861(p), and 1861(cc) of such Act (42 U.S.C.*
 19 *1395n(a)(2), 1395x(p), and 1395x(cc), respectively)*
 20 *shall be applied—*

21 (A) *without regard to any requirement*
 22 *that—*

23 (i) *an individual be under the care of*
 24 *(or referred by) a physician; or*

1 (ii) services be provided under the su-
2 pervision of a physician; and

3 (B) by allowing a physician or a qualified
4 physical therapist to satisfy any requirement
5 for—

6 (i) certification and recertification;
7 and

8 (ii) establishment and periodic review
9 of a plan of care.

10 (3) *FEE-FOR-SERVICE MEDICARE BENE-*
11 *FICIARY.*—The term “fee-for-service medicare bene-
12 ficiary” means an individual who—

13 (A) is enrolled under part B of title XVIII
14 of the Social Security Act (42 U.S.C. 1395j et
15 seq.); and

16 (B) is not enrolled in—

17 (i) a Medicare+Choice plan under
18 part C of such title (42 U.S.C. 1395w–21 et
19 seq.);

20 (ii) a plan offered by an eligible orga-
21 nization under section 1876 of such Act (42
22 U.S.C. 1395mm);

23 (iii) a program of all-inclusive care for
24 the elderly (PACE) under section 1894 of
25 such Act (42 U.S.C. 1395eee); or

1 (iv) a social health maintenance orga-
 2 nization (SHMO) demonstration project es-
 3 tablished under section 4018(b) of the Om-
 4 nibus Budget Reconciliation Act of 1987
 5 (Public Law 100–203).

6 (4) *OUTPATIENT PHYSICAL THERAPY SERV-*
 7 *ICES.*—Subject to paragraph (2), the term “outpatient
 8 physical therapy services” has the meaning given to
 9 such term in section 1861(p) of the Social Security
 10 Act (42 U.S.C. 1395x(p)), except that such term shall
 11 not include the speech-language pathology services de-
 12 scribed in the fourth sentence of such section.

13 (5) *PHYSICIAN.*—The term “physician” has the
 14 meaning given to such term in section 1861(r)(1) of
 15 such Act (42 U.S.C. 1395x(r)(1)).

16 (6) *QUALIFIED PHYSICAL THERAPIST.*—The term
 17 “qualified physical therapist” has the meaning given
 18 to such term for purposes of section 1861(p) of such
 19 Act (42 U.S.C. 1395x(p)), as in effect on the date of
 20 enactment of this Act.

21 **SEC. 450. DEMONSTRATION PROJECT TO CLARIFY THE DEF-**
 22 **INITION OF HOMEBOUND.**

23 (a) *DEMONSTRATION PROJECT.*—Not later than 180
 24 days after the date of enactment of this Act, the Secretary
 25 shall conduct a two-year demonstration project under part

1 *B of title XVIII of the Social Security Act under which*
 2 *medicare beneficiaries with chronic conditions described in*
 3 *subsection (b) are deemed to be homebound for purposes of*
 4 *receiving home health services under the medicare program.*

5 *(b) MEDICARE BENEFICIARY DESCRIBED.—For pur-*
 6 *poses of subsection (a), a medicare beneficiary is eligible*
 7 *to be deemed to be homebound, without regard to the pur-*
 8 *pose, frequency, or duration of absences from the home, if*
 9 *the beneficiary—*

10 *(1) has been certified by one physician as an in-*
 11 *dividual who has a permanent and severe condition*
 12 *that will not improve;*

13 *(2) requires the individual to receive assistance*
 14 *from another individual with at least 3 out of the 5*
 15 *activities of daily living for the rest of the individ-*
 16 *ual's life;*

17 *(3) requires 1 or more home health services to*
 18 *achieve a functional condition that gives the indi-*
 19 *vidual the ability to leave home; and*

20 *(4) requires technological assistance or the assist-*
 21 *ance of another person to leave the home.*

22 *(c) DEMONSTRATION PROJECT SITES.—The dem-*
 23 *onstration project established under this section shall be*
 24 *conducted in 3 States selected by the Secretary to represent*

1 *the Northeast, Midwest, and Western regions of the United*
2 *States.*

3 (d) *LIMITATION ON NUMBER OF PARTICIPANTS.—The*
4 *aggregate number of such beneficiaries that may participate*
5 *in the project may not exceed 15,000.*

6 (e) *DATA.—The Secretary shall collect such data on*
7 *the demonstration project with respect to the provision of*
8 *home health services to medicare beneficiaries that relates*
9 *to quality of care, patient outcomes, and additional costs,*
10 *if any, to the medicare program.*

11 (f) *REPORT TO CONGRESS.—Not later than 1 year*
12 *after the date of the completion of the demonstration project*
13 *under this section, the Secretary shall submit to Congress*
14 *a report on the project using the data collected under sub-*
15 *section (e) and shall include—*

16 (1) *an examination of whether the provision of*
17 *home health services to medicare beneficiaries under*
18 *the project—*

19 (A) *adversely effects the provision of home*
20 *health services under the medicare program; or*

21 (B) *directly causes an unreasonable increase*
22 *of expenditures under the medicare program for*
23 *the provision of such services that is directly at-*
24 *tributable to such clarification;*

1 (2) *the specific data evidencing the amount of*
 2 *any increase in expenditures that is a directly attrib-*
 3 *utable to the demonstration project (expressed both in*
 4 *absolute dollar terms and as a percentage) above ex-*
 5 *penditures that would otherwise have been incurred*
 6 *for home health services under the medicare program;*
 7 *and*

8 (3) *specific recommendations to exempt perma-*
 9 *nently and severely disabled homebound beneficiaries*
 10 *from restrictions on the length, frequency and purpose*
 11 *of their absences from the home to qualify for home*
 12 *health services without incurring additional unrea-*
 13 *sonable costs to the medicare program.*

14 (g) *WAIVER AUTHORITY.—The Secretary shall waive*
 15 *compliance with the requirements of title XVIII of the So-*
 16 *cial Security Act (42 U.S.C. 1395 et seq.) to such extent*
 17 *and for such period as the Secretary determines is necessary*
 18 *to conduct demonstration projects.*

19 (h) *CONSTRUCTION.—Nothing in this section shall be*
 20 *construed as waiving any applicable civil monetary pen-*
 21 *alty, criminal penalty, or other remedy available to the Sec-*
 22 *retary under title XI or title XVIII of the Social Security*
 23 *Act for acts prohibited under such titles, including penalties*
 24 *for false certifications for purposes of receipt of items or*
 25 *services under the medicare program.*

1 (i) *AUTHORIZATION OF APPROPRIATIONS.*—*Payments*
 2 *for the costs of carrying out the demonstration project under*
 3 *this section shall be made from the Federal Supplementary*
 4 *Insurance Trust Fund under section 1841 of such Act (42*
 5 *U.S.C. 1395t).*

6 (j) *DEFINITIONS.*—*In this section:*

7 (1) *MEDICARE BENEFICIARY.*—*The term “medi-*
 8 *care beneficiary” means an individual who is enrolled*
 9 *under part B of title XVIII of the Social Security*
 10 *Act.*

11 (2) *HOME HEALTH SERVICES.*—*The term “home*
 12 *health services” has the meaning given such term in*
 13 *section 1861(m) of the Social Security Act (42 U.S.C.*
 14 *1395x(m)).*

15 (3) *ACTIVITIES OF DAILY LIVING DEFINED.*—*The*
 16 *term “activities of daily living” means eating,*
 17 *toileting, transferring, bathing, and dressing.*

18 (4) *SECRETARY.*—*The term “Secretary” means*
 19 *the Secretary of Health and Human Services.*

20 **SEC. 450A. DEMONSTRATION PROJECT FOR EXCLUSION OF**
 21 **BRACHYTHERAPY DEVICES FROM PROSPEC-**
 22 **TIVE PAYMENT SYSTEM FOR OUTPATIENT**
 23 **HOSPITAL SERVICES.**

24 (a) *DEMONSTRATION PROJECT.*—*The Secretary shall*
 25 *conduct a demonstration project under part B of title XVIII*

1 *of the Social Security Act under which brachytherapy de-*
 2 *vices shall be excluded from the prospective payment system*
 3 *for outpatient hospital services under the medicare program*
 4 *and, notwithstanding section 1833(t) of the Social Security*
 5 *Act (42 U.S.C. 1395l(t)), the amount of payment for a de-*
 6 *vice of brachytherapy furnished under the demonstration*
 7 *project shall be equal to the hospital's charges for each de-*
 8 *vice furnished, adjusted to cost.*

9 **(b) SPECIFICATION OF GROUPS FOR BRACHYTHERAPY**
 10 *DEVICES.—The Secretary shall create additional groups of*
 11 *covered OPD services that classify devices of brachytherapy*
 12 *furnished under the demonstration project separately from*
 13 *the other services (or group of services) paid for under sec-*
 14 *tion 1833(t) of the Social Security Act (42 U.S.C. 1395l(t))*
 15 *in a manner reflecting the number, isotope, and radioactive*
 16 *intensity of such devices furnished, including separate*
 17 *groups for palladium–103 and iodine–125 devices.*

18 **(c) DURATION.—***The Secretary shall conduct the dem-*
 19 *onstration project under this section for the 3-year period*
 20 *beginning on the date that is 90 days after the date of enact-*
 21 *ment of this Act.*

22 **(d) REPORT.—***Not later than January 1, 2007, the*
 23 *Secretary shall submit to Congress a report on the dem-*
 24 *onstration project conducted under this section. The report*
 25 *shall include an evaluation of patient outcomes under the*

1 demonstration project, as well as an analysis of the cost
 2 effectiveness of the demonstration project.

3 (e) *WAIVER AUTHORITY.*—The Secretary shall waive
 4 compliance with the requirements of title XVIII of the So-
 5 cial Security Act to such extent and for such period as the
 6 Secretary determines is necessary to conduct the demonstra-
 7 tion project under this section.

8 (f) *FUNDING.*—

9 (1) *IN GENERAL.*—The Secretary shall provide
 10 for the transfer from the Federal Supplementary In-
 11 surance Trust Fund established under section 1841 of
 12 the Social Security Act (42 U.S.C. 1395t) of such
 13 funds as are necessary for the costs of carrying out
 14 the demonstration project under this section.

15 (2) *BUDGET NEUTRALITY.*—In conducting the
 16 demonstration project under this section, the Sec-
 17 retary shall ensure that the aggregate payments made
 18 by the Secretary do not exceed the amount which the
 19 Secretary would have paid if the demonstration
 20 project under this section was not implemented.

21 **SEC. 450B. REIMBURSEMENT FOR TOTAL BODY ORTHOTIC**
 22 **MANAGEMENT FOR CERTAIN NURSING HOME**
 23 **PATIENTS.**

24 (a) *IN GENERAL.*—Not later than 60 days after the
 25 date of the enactment of this Act, the Secretary shall issue

1 *product codes that qualified practioners and suppliers may*
 2 *use to receive reimbursement under section 1834(h) of the*
 3 *Social Security Act (42 U.S.C. 1395m(h)) for qualified*
 4 *total body orthotic management devices used for the treat-*
 5 *ment of nonambulatory individuals with severe musculo-*
 6 *skeletal conditions who are in the full-time care of skilled*
 7 *nursing facilities (as defined in section 1861(j) of such Act*
 8 *(42 U.S.C. 1395x(j))). In issuing such codes, the Secretary*
 9 *shall take all steps necessary to prevent fraud and abuse.*

10 *(b) QUALIFIED TOTAL BODY ORTHOTIC MANAGEMENT*
 11 *DEVICE.—For purposes of this section, the term “qualified*
 12 *total body orthotic management device” means a medically-*
 13 *prescribed device which—*

14 *(1) consists of custom fitted individual braces*
 15 *with adjustable points at the hips, knee, ankle, elbow,*
 16 *and wrist, but only if—*

17 *(A) the individually adjustable braces are*
 18 *attached to a frame which is an integral compo-*
 19 *nent of the device and cannot function or be used*
 20 *apart from the frame; and*

21 *(B) the frame is designed such that it serves*
 22 *no purpose without the braces; and*

23 *(2) is designed to—*

24 *(A) improve function;*

1 (B) retard progression of musculoskeletal
2 deformity; or

3 (C) restrict, eliminate, or assist in the func-
4 tioning of lower and upper extremities and pel-
5 vic, spinal, and cervical regions of the body af-
6 fected by injury, weakness, or deformity,
7 of an individual for whom stabilization of affected
8 areas of the body, or relief of pressure points, is re-
9 quired for medical reasons.

10 **SEC. 450C. AUTHORIZATION OF REIMBURSEMENT FOR ALL**
11 **MEDICARE PART B SERVICES FURNISHED BY**
12 **CERTAIN INDIAN HOSPITALS AND CLINICS.**

13 (a) *IN GENERAL.*—Section 1880(e) (42 U.S.C.
14 1395qq(e)) is amended—

15 (1) in paragraph (1)(A), by striking “for services
16 described in paragraph (2)” and inserting “for all
17 items and services for which payment may be made
18 under such part”;

19 (2) by striking paragraph (2); and

20 (3) by redesignating paragraph (3) as para-
21 graph (2).

22 (b) *EFFECTIVE DATE.*—The amendments made by this
23 section shall apply to items and services furnished on or
24 after October 1, 2004.

1 **SEC. 450D. COVERAGE OF CARDIOVASCULAR SCREENING**

2 **TESTS.**

3 (a) *COVERAGE.*—Section 1861(s)(2) of the Social Secu-
4 rity Act (42 U.S.C. 1395x(s)(2)) is amended—

5 (1) in subparagraph (U), by striking “and” at
6 the end;

7 (2) in subparagraph (V)(iii), by inserting “and”
8 at the end; and

9 (3) by adding at the end the following new sub-
10 paragraph:

11 “(W) cardiovascular screening tests (as de-
12 fined in subsection (ww)(1));”.

13 (b) *SERVICES DESCRIBED.*—Section 1861 of the Social
14 Security Act (42 U.S.C. 1395x) is amended by adding at
15 the end the following new subsection:

16 “Cardiovascular Screening Tests

17 “(ww)(1) The term ‘cardiovascular screening tests’
18 means the following diagnostic tests for the early detection
19 of cardiovascular disease:

20 “(A) Tests for the determination of cholesterol
21 levels.

22 “(B) Tests for the determination of lipid levels of
23 the blood.

24 “(C) Such other tests for cardiovascular disease
25 as the Secretary may approve.

1 “(2)(A) *Subject to subparagraph (B), the Secretary*
 2 *shall establish standards, in consultation with appropriate*
 3 *organizations, regarding the frequency and type of cardio-*
 4 *vascular screening tests.*

5 “(B) *With respect to the frequency of cardiovascular*
 6 *screening tests approved by the Secretary under subpara-*
 7 *graph (A), in no case may the frequency of such tests be*
 8 *more often than once every 2 years.”.*

9 (c) *FREQUENCY.*—Section 1862(a)(1) of the Social Se-
 10 *curity Act (42 U.S.C. 1395y(a)(1)) is amended—*

11 (1) *by striking “and” at the end of subpara-*
 12 *graph (H);*

13 (2) *by striking the semicolon at the end of sub-*
 14 *paragraph (I) and inserting “, and”; and*

15 (3) *by adding at the end the following new sub-*
 16 *paragraph:*

17 “(J) *in the case of a cardiovascular screening*
 18 *test (as defined in section 1861(ww)(1)), which is per-*
 19 *formed more frequently than is covered under section*
 20 *1861(ww)(2).”.*

21 (d) *EFFECTIVE DATE.*—*The amendments made by this*
 22 *section shall apply to tests furnished on or after January*
 23 *1, 2005.*

1 **SEC. 450E. MEDICARE COVERAGE OF SELF-INJECTED**
 2 **BIOLOGICALS.**

3 (a) *COVERAGE.*—

4 (1) *IN GENERAL.*—Section 1861(s)(2) (42 U.S.C.
 5 1395x(s)(2)) is amended—

6 (A) in subparagraph (U), by striking “and”
 7 at the end;

8 (B) in subparagraph (V), by inserting
 9 “and” at the end; and

10 (C) by adding at the end the following new
 11 subparagraph:

12 “(W)(i) a self-injected biological (which is ap-
 13 proved by the Food and Drug Administration) that is
 14 prescribed as a complete replacement for a drug or bi-
 15 ological (including the same biological for which pay-
 16 ment is made under this title when it is furnished in-
 17 cident to a physicians’ service) that would otherwise
 18 be described in subparagraph (A) or (B) and that is
 19 furnished during 2004 or 2005; and

20 “(ii) a self-injected drug that is used to treat
 21 multiple sclerosis;”.

22 (2) *CONFORMING AMENDMENT.*—Subparagraphs
 23 (A) and (B) of section 1861(s)(2) of the Social Secu-
 24 rity Act (42 U.S.C. 1395x(s)(2)) are each amended by
 25 inserting “, except for any drug or biological de-
 26 scribed in subparagraph (W),” after “which”.

1 (b) *EFFECTIVE DATE.*—*The amendments made by sub-*
 2 *section (a) shall apply to drugs and biologicals furnished*
 3 *on or after January 1, 2004 and before January 1, 2006.*

4 **SEC. 450F. EXTENSION OF MEDICARE SECONDARY PAYER**
 5 **RULES FOR INDIVIDUALS WITH END-STAGE**
 6 **RENAL DISEASE.**

7 *Section 1862(b)(1)(C) (42 U.S.C. 1395y(b)(1)(C)) is*
 8 *amended—*

9 (1) *in the last sentence, by inserting “, and be-*
 10 *fore January 1, 2004” after “prior to such date”;*
 11 *and*

12 (2) *by adding at the end the following new sen-*
 13 *tence: “Effective for items and services furnished on*
 14 *or after January 1, 2004 (with respect to periods be-*
 15 *ginning on or after June 1, 2002), clauses (i) and (ii)*
 16 *shall be applied by substituting ‘36-month’ for ‘12-*
 17 *month’ each place it appears in the first sentence.*

18 **SEC. 450G. REQUIRING THE INTERNAL REVENUE SERVICE**
 19 **TO DEPOSIT INSTALLMENT AGREEMENT AND**
 20 **OTHER FEES IN THE TREASURY AS MISCELLA-**
 21 **NEOUS RECEIPTS.**

22 *Notwithstanding any other provision of law, the Sec-*
 23 *retary of the Treasury is required to deposit in the Treasury*
 24 *as miscellaneous receipts any fee receipts, including fees*
 25 *from installment agreements and restructured installment*

1 *agreements, collected under the authority provided by Sec-*
 2 *tion 3 of the Administrative Provisions of the Internal Rev-*
 3 *enue Service of Public Law 103–329, the Treasury, Postal*
 4 *Service and General Government Appropriations Act, 1995.*
 5 *Fees collected under this section shall be available for use*
 6 *by the Internal Revenue Service only to the extent that such*
 7 *authority is provided in advance in an appropriations Act.*

8 **SEC. 450H INCREASING TYPES OF ORIGINATING TELE-**
 9 **HEALTH SITES AND FACILITATING THE PRO-**
 10 **VISION OF TELEHEALTH SERVICES ACROSS**
 11 **STATE LINES.**

12 *(a) INCREASING TYPES OF ORIGINATING SITES.—Sec-*
 13 *tion 1834(m)(4)(C)(ii) (42 U.S.C. 1395m(m)(4)(C)(ii)) is*
 14 *amended by adding at the end the following new subclauses:*

15 *“(VI) A skilled nursing facility*
 16 *(as defined in section 1819(a)).*

17 *“(VII) An assisted-living facility*
 18 *(as defined by the Secretary).*

19 *“(VIII) A board-and-care home*
 20 *(as defined by the Secretary).*

21 *“(IX) A county of community*
 22 *health clinic (as defined by the Sec-*
 23 *retary).*

1 “(X) A community mental health
 2 center (as described in section
 3 1861(ff)(2)(B)).

4 “(XI) A long-term care facility
 5 (as defined by the Secretary).

6 “(XII) A facility operated by the
 7 Indian Health Service or by an Indian
 8 tribe, tribal organization, or an urban
 9 Indian organization (as such terms are
 10 defined in section 4 of the Indian
 11 Health Care Improvement Act (25
 12 U.S.C. 1603)) directly, or under con-
 13 tract or other arrangement.”.

14 (b) *FACILITATING THE PROVISION OF TELEHEALTH*
 15 *SERVICES ACROSS STATE LINES.*—

16 (1) *IN GENERAL.*—For purposes of expediting the
 17 provision of telehealth services for which payment is
 18 made under the medicare program under section
 19 1834(m) of the Social Security Act (42 U.S.C.
 20 1395m(m)), across State lines, the Secretary shall, in
 21 consultation with representatives of States, physi-
 22 cians, health care practitioners, and patient advo-
 23 cates, encourage and facilitate the adoption of State
 24 provisions allowing for multistate practitioner licen-
 25 sure across State lines.

1 (2) *DEFINITIONS.—In this subsection:*

2 (A) *TELEHEALTH SERVICE.—The term*
 3 *“telehealth service” has the meaning given that*
 4 *term in subparagraph (F)(i) of section*
 5 *1834(m)(4) of the Social Security Act (42 U.S.C.*
 6 *1395m(m)(4)).*

7 (B) *PHYSICIAN, PRACTITIONER.—The terms*
 8 *“physician” and “practitioner” have the mean-*
 9 *ing given those terms in subparagraphs (D) and*
 10 *(E), respectively, of such section.*

11 (C) *MEDICARE PROGRAM.—The term*
 12 *“medicare program” means the program of*
 13 *health insurance administered by the Secretary*
 14 *under title XVIII of the Social Security Act (42*
 15 *U.S.C. 1395 et seq.).*

16 **SEC. 450I. DEMONSTRATION PROJECT FOR COVERAGE OF**
 17 **SURGICAL FIRST ASSISTING SERVICES OF**
 18 **CERTIFIED REGISTERED NURSE FIRST AS-**
 19 **SISTANTS.**

20 (a) *DEMONSTRATION PROJECT.—The Secretary shall*
 21 *conduct a demonstration project under part B of title XVIII*
 22 *of the Social Security Act under which payment is made*
 23 *for surgical first assisting services furnished by a certified*
 24 *registered nurse first assistant to medicare beneficiaries.*

25 (b) *DEFINITIONS.—In this section:*

1 (1) *SURGICAL FIRST ASSISTING SERVICES.*—The
 2 term “surgical first assisting services” means services
 3 consisting of first assisting a physician with surgery
 4 and related preoperative, intraoperative, and post-
 5 operative care (as determined by the Secretary) fur-
 6 nished by a certified registered nurse first assistant
 7 (as defined in paragraph (2)) which the certified reg-
 8 istered nurse first assistant is legally authorized to
 9 perform by the State in which the services are per-
 10 formed.

11 (2) *CERTIFIED REGISTERED NURSE FIRST AS-*
 12 *SISTANT.*—The term “certified registered nurse first
 13 assistant” means an individual who—

14 (A) is a registered nurse and is licensed to prac-
 15 tice nursing in the State in which the surgical first
 16 assisting services are performed;

17 (B) has completed a minimum of 2,000 hours of
 18 first assisting a physician with surgery and related
 19 preoperative, intraoperative, and postoperative care;
 20 and

21 (C) is certified as a registered nurse first assist-
 22 ant by an organization recognized by the Secretary.

23 (c) *PAYMENT RATES.*—Payment under the demonstra-
 24 tion project for surgical first assisting services furnished by
 25 a certified registered nurse first assistant shall be made at

1 *the rate of 80 percent of the lesser of the actual charge for*
 2 *the services or 85 percent of the amount determined under*
 3 *the fee schedule established under section 1848(b) of the So-*
 4 *cial Security Act (42 U.S.C. 1395w-4(b)) for the same serv-*
 5 *ices if furnished by a physician.*

6 (d) *DEMONSTRATION PROJECT SITES.*—*The project es-*
 7 *tablished under this section shall be conducted in 5 States*
 8 *selected by the Secretary.*

9 (e) *DURATION.*—*The Secretary shall conduct the dem-*
 10 *onstration project for the 3-year period beginning on the*
 11 *date that is 90 days after the date of the enactment of this*
 12 *Act.*

13 (f) *REPORT.*—*Not later than January 1, 2007, the Sec-*
 14 *retary shall submit to Congress a report on the project. The*
 15 *report shall include an evaluation of patient outcomes*
 16 *under the project, as well as an analysis of the cost effective-*
 17 *ness of the project.*

18 (g) *FUNDING.*—

19 (1) *IN GENERAL.*—*The Secretary shall provide*
 20 *for the transfer from the Federal Supplementary In-*
 21 *surance Trust Fund established under section 1841 of*
 22 *the Social Security Act (42 U.S.C. 1395t) of such*
 23 *funds as are necessary for the costs of carrying out*
 24 *the project under this section.*

1 (2) *BUDGET NEUTRALITY.*—*In conducting the*
 2 *project under this section, the Secretary shall ensure*
 3 *that the aggregate payments made by the Secretary*
 4 *do not exceed the amount which the Secretary would*
 5 *have paid if the project under this section was not*
 6 *implemented.*

7 (i) *WAIVER AUTHORITY.*—*The Secretary shall waive*
 8 *compliance with the requirements of title XVIII of the So-*
 9 *cial Security Act to such extent and for such period as the*
 10 *Secretary determines is necessary to conduct demonstration*
 11 *projects.*

12 **SEC. 450J. EQUITABLE TREATMENT FOR CHILDREN’S HOS-**
 13 **PITALS.**

14 (a) *IN GENERAL.*—*Section 1833(t)(7)(D)(ii) (42*
 15 *U.S.C. 1395l(t)(7)(D)(ii)) is amended to read as follows:*

16 “(i) *PERMANENT TREATMENT FOR*
 17 *CANCER HOSPITALS AND CHILDREN’S HOS-*
 18 *PITALS.*—

19 “(I) *IN GENERAL.*—*Subject to*
 20 *subclause (II), in the case of a hospital*
 21 *described in clause (iii) or (v) of sec-*
 22 *tion 1886(d)(1)(B), for covered OPD*
 23 *services for which the PPS amount is*
 24 *less than the pre-BBA amount, the*
 25 *amount of payment under this sub-*

1 section shall be increased by the
2 amount of such difference.

3 “(II) *SPECIAL RULE FOR CERTAIN*
4 *CHILDREN’S HOSPITALS.*—In the case
5 of a hospital described in section
6 1886(d)(1)(B)(iii) that is located in a
7 State with a reimbursement system
8 under section 1814(b)(3), but that is
9 not reimbursed under such system, for
10 covered OPD services furnished on or
11 after October 1, 2003, and for which
12 the PPS amount is less than the great-
13 er of the pre-BBA amount or the rea-
14 sonable operating and capital costs
15 without reductions of the hospital in
16 providing such services, the amount of
17 payment under this subsection shall be
18 increased by the amount of such dif-
19 ference.”.

20 **SEC. 450K. TREATMENT OF PHYSICIANS’ SERVICES FUR-**
21 **NISHED IN ALASKA.**

22 Section 1848(b) (42 U.S.C. 1395w–4(b)) is amended—
23 (1) in paragraph (1), in the matter preceding
24 subparagraph (A), by striking “paragraph (2)” and
25 inserting “paragraphs (2) and (4)”; and

1 (2) *by adding at the end the following new para-*
 2 *graph:*

3 “(4) *TREATMENT OF PHYSICIANS’ SERVICES FUR-*
 4 *NISHED IN ALASKA.—*

5 “(A) *IN GENERAL.—With respect to physi-*
 6 *cians’ services furnished in Alaska on or after*
 7 *January 1, 2004, and before January 1, 2006,*
 8 *the fee schedule for such services shall be deter-*
 9 *mined as follows:*

10 “(i) *Subject to clause (ii), the payment*
 11 *amount for a service furnished in a year*
 12 *shall be an amount equal to—*

13 “(I) *in the case of services fur-*
 14 *nished in calendar year 2004, 90 per-*
 15 *cent of the VA Alaska fee schedule*
 16 *amount for the service for fiscal year*
 17 *2001; and*

18 “(II) *in the case of services fur-*
 19 *nished in calendar year 2005, the*
 20 *amount determined under subclause (I)*
 21 *for 2004, increased by the annual up-*
 22 *date determined under subsection (d)*
 23 *for the year involved.*

24 “(ii) *In the case of a service for which*
 25 *there was no VA Alaska fee schedule amount*

1 *for fiscal year 2001, the payment amount*
 2 *shall be an amount equal to the sum of—*

3 “(I) *the amount of payment for*
 4 *the service that would otherwise apply*
 5 *under this section; plus*

6 “(II) *an amount equal to the ap-*
 7 *plicable percent (as described in sub-*
 8 *paragraph (C)) of the amount de-*
 9 *scribed in subclause (I).*

10 “(B) VA ALASKA FEE SCHEDULE
 11 *AMOUNT.—For purposes of this paragraph, the*
 12 *term ‘VA Alaska fee schedule amount’ means the*
 13 *amount that was paid by the Department of Vet-*
 14 *erans Affairs in Alaska in fiscal year 2001 for*
 15 *non-Department of Veterans Affairs physicians’*
 16 *services associated with either outpatient or in-*
 17 *patient care provided to individuals eligible for*
 18 *hospital care or medical services under chapter*
 19 *17 of title 38, United States Code, at a non-De-*
 20 *partment facility (as that term is defined in sec-*
 21 *tion 1701(4) of such title 38.*

22 “(C) *APPLICABLE PERCENT.—For purposes*
 23 *of this paragraph, the term ‘applicable percent’*
 24 *means the weighted average percentage (based on*
 25 *claims under this section) by which the fiscal*

1 year 2001 VA Alaska fee schedule amount for
 2 physicians' services exceeded the amount of pay-
 3 ment for such services under this section that ap-
 4 plied in Alaska in 2001.”.

5 **SEC. 450L. DEMONSTRATION PROJECT TO EXAMINE WHAT**
 6 **WEIGHT LOSS WEIGHT MANAGEMENT SERV-**
 7 **ICES CAN COST EFFECTIVELY REACH THE**
 8 **SAME RESULT AS THE NIH DIABETES PRI-**
 9 **MARY PREVENTION TRIAL STUDY: A 50 PER-**
 10 **CENT REDUCTION IN THE RISK FOR TYPE 2**
 11 **DIABETES FOR INDIVIDUALS WHO HAVE IM-**
 12 **PAIRED GLUCOSE TOLERANCE AND ARE**
 13 **OBESE.**

14 (a) *IN GENERAL.*—Inasmuch as the NIH Diabetes Pri-
 15 mary Prevention Trial study proved that the risk of type
 16 2 diabetes could be cut in half when the Institute of Medi-
 17 cine definition of successful weight loss (5 percent weight
 18 loss maintained for a year) is achieved by individuals at
 19 risk for type 2 diabetes due to obesity and impaired glucose
 20 tolerance, the Secretary shall conduct a demonstration
 21 project to examine the cost effectiveness and health benefits
 22 of providing group weight loss management services to
 23 achieve the same result for beneficiaries under the medicare
 24 program under title XVIII of the Social Security Act who
 25 are obese and have impaired glucose tolerance.

1 (b) *LIMITATION.*—*The cost of the group weight loss*
 2 *management services provided under subsection (a) shall*
 3 *not exceed the cost per recipient per year of the medical*
 4 *nutritional therapy benefit currently available to medicare*
 5 *beneficiaries.*

6 (c) *SCOPE OF SERVICES.*—

7 (1) *DURATION.*—*The project shall be conducted*
 8 *for a period of 2 fiscal years.*

9 (2) *SITES.*—*The Secretary shall designate the*
 10 *sites at which to conduct the demonstration program*
 11 *under this section. In selecting sites under this para-*
 12 *graph, the Secretary shall give preference to sites lo-*
 13 *cated in—*

14 (A) *rural areas; or*

15 (B) *areas that have a high concentration of*
 16 *Native Americans with type 2 diabetes.*

17 (3) *FUNDING.*—

18 (A) *IN GENERAL.*—*Subject to subparagraph*
 19 *(B), the Secretary shall provide for the transfer*
 20 *from the Federal Supplementary Insurance*
 21 *Trust Fund established under section 1841 of*
 22 *such Act (42 U.S.C. 1395t) of such funds as are*
 23 *necessary for the costs of carrying out the dem-*
 24 *onstration program under this section.*

1 (B) *LIMITATION.*—*The total amount of the*
 2 *payments that may be made under this section*
 3 *shall not exceed \$2,500,000 for each fiscal year*
 4 *in which the project is conducted under para-*
 5 *graph (1).*

6 (d) *COVERAGE AS MEDICARE PART B SERVICES.*—

7 (1) *IN GENERAL.*—*Subject to the succeeding pro-*
 8 *visions of this subsection, medical nutrition therapy*
 9 *services furnished under the project shall be consid-*
 10 *ered to be services covered under part B of title XVIII*
 11 *of the Social Security Act (42 U.S.C. 1395j et seq.).*

12 (2) *PAYMENT.*—*Payment for such services shall*
 13 *be made at a rate of 80 percent of the lesser of the*
 14 *actual charge for the services or 85 percent of the fee*
 15 *schedule amount provided under section 1848 of the*
 16 *Social Security Act (42 U.S.C. 139w-4) for the same*
 17 *services if such services were furnished by a physi-*
 18 *cian.*

19 (3) *APPLICATION OF LIMITS OF BILLING.*—*The*
 20 *provisions of section 1842(b)(18) of the Social Secu-*
 21 *rity Act (42 U.S.C. 1395u(b)(18)) shall apply to a*
 22 *group weight loss management professional furnishing*
 23 *services under the project in the same manner as they*
 24 *to a practitioner described in subparagraph (C) of*

1 *such section furnishing services under title XVIII of*
 2 *such Act.*

3 (e) *REPORTS.*—*The Secretary shall submit to the Com-*
 4 *mittee on Ways and Means and the Committee on Com-*
 5 *merce of the House of Representatives and the Committee*
 6 *on Finance of the Senate interim reports on the project and*
 7 *a final report on the project not later than the date that*
 8 *is 6 months after the date on which the project concludes.*
 9 *The final report shall include an evaluation of the impact*
 10 *of the use of group weight loss management services as part*
 11 *of medical nutrition therapy on medicare beneficiaries and*
 12 *on the medicare program, including any impact on reduc-*
 13 *ing costs under the program and improving the health of*
 14 *beneficiaries.*

15 (f) *DEFINITIONS.*—*For purposes of this section:*

16 (1) *The term “obesity” means that an individual*
 17 *has a Body Mass Index (BMI) of 30 and above.*

18 (2) *GROUP WEIGHT LOSS MANAGEMENT SERV-*
 19 *ICES.*—*The term “group weight loss management*
 20 *services” means comprehensive services furnished to*
 21 *individuals who have been diagnosed and referred by*
 22 *a physician as having impaired glucose tolerance and*
 23 *who are obese that consist of—*

1 (A) assessment and treatment based on the
 2 needs of individuals as determined by a group
 3 weight loss management professional; or

4 (B) a specific program or method that has
 5 demonstrated its efficacy to produce and main-
 6 tain weight loss through results published in
 7 peer-reviewed scientific journals using recognized
 8 research methods and statistical analysis that
 9 provides—

10 (i) assessment of current body weight
 11 and recording of weight status at each meet-
 12 ing session;

13 (ii) provision of a healthy eating plan;

14 (iii) provision of an activity plan;

15 (iv) provision of a behavior modifica-
 16 tion plan; and

17 (v) a weekly group support meeting.

18 (3) *GROUP WEIGHT LOSS MANAGEMENT PROFES-*
 19 *SIONAL.*—The term “group weight loss management
 20 professional” means an individual who has completed
 21 training to provide a program or method that has
 22 completed clinical trials and has demonstrated its ef-
 23 ficacy through publications in peer-reviewed scientific
 24 journals who—

1 (A)(i) holds a baccalaureate or higher de-
 2 gree granted by a regionally accredited college or
 3 university in the United States (or an equivalent
 4 foreign degree) in nutrition social work, psy-
 5 chology with experience in behavioral modifica-
 6 tion methods to reduce obesity; or

7 (ii) has completed a curriculum of training
 8 for a specific behavioral based weight manage-
 9 ment program as described in section (4)(A)(2)
 10 and recommended in the NIH Clinical Guide-
 11 lines on Identification, Evaluation, and Treat-
 12 ment of Overweight and Obesity in Adults, chap-
 13 ter 4, section H, parts 1, 2, 3, 4, and pursuant
 14 to guidelines by the Secretary; and

15 (B)(i) is licensed or certified as a group
 16 weight loss management professional by the
 17 State in which the services are performed; or

18 (ii) is certified by an organization that
 19 meets such criteria as the Secretary establishes
 20 with—

21 (I) national organizations representing
 22 consumers such as the American Obesity As-
 23 sociation and the elderly; and

24 (II) such other organizations as the
 25 Secretary determines appropriate.

1 ***Subtitle C—Provisions Relating to***
 2 ***Parts A and B***

3 ***SEC. 451. INCREASE FOR HOME HEALTH SERVICES FUR-***
 4 ***NISHED IN A RURAL AREA.***

5 (a) *IN GENERAL.*—*In the case of home health services*
 6 *furnished in a rural area (as defined in section*
 7 *1886(d)(2)(D) of the Social Security Act (42 U.S.C.*
 8 *1395ww(d)(2)(D))) on or after October 1, 2004, and before*
 9 *October 1, 2006, the Secretary shall increase the payment*
 10 *amount otherwise made under section 1895 of such Act (42*
 11 *U.S.C. 1395fff) for such services by 5 percent.*

12 (b) *WAIVING BUDGET NEUTRALITY.*—*The Secretary*
 13 *shall not reduce the standard prospective payment amount*
 14 *(or amounts) under section 1895 of the Social Security Act*
 15 *(42 U.S.C. 1395fff) applicable to home health services fur-*
 16 *nished during a period to offset the increase in payments*
 17 *resulting from the application of subsection (a).*

18 (c) *NO EFFECT ON SUBSEQUENT PERIODS.*—*The pay-*
 19 *ment increase provided under subsection (a) for a period*
 20 *under such subsection—*

21 (1) *shall not apply to episodes and visits ending*
 22 *after such period; and*

23 (2) *shall not be taken into account in calculating*
 24 *the payment amounts applicable for episodes and vis-*
 25 *its occurring after such period.*

1 **SEC. 452. LIMITATION ON REDUCTION IN AREA WAGE AD-**
 2 **JUSTMENT FACTORS UNDER THE PROSPEC-**
 3 **TIVE PAYMENT SYSTEM FOR HOME HEALTH**
 4 **SERVICES.**

5 *Section 1895(b)(4)(C) (42 U.S.C. 1395fff(b)(4)(C)) is*
 6 *amended—*

7 *(1) by striking “FACTORS.—The Secretary” and*
 8 *inserting “FACTORS.—*

9 *“(i) IN GENERAL.—Subject to clause*
 10 *(ii), the Secretary”; and*

11 *(2) by adding at the end the following new*
 12 *clause:*

13 *“(ii) LIMITATION ON REDUCTION IN*
 14 *FISCAL YEAR 2005 AND 2006.—For fiscal*
 15 *years 2005 and 2006, the area wage adjust-*
 16 *ment factor applicable to home health serv-*
 17 *ices furnished in an area in the fiscal year*
 18 *may not be more that 3 percent less than*
 19 *the area wage adjustment factor applicable*
 20 *to home health services for the area for the*
 21 *previous year.”.*

22 **SEC. 453. CLARIFICATIONS TO CERTAIN EXCEPTIONS TO**
 23 **MEDICARE LIMITS ON PHYSICIAN REFER-**
 24 **RALS.**

25 *(a) LIMITS ON PHYSICIAN REFERRALS.—*

1 (1) *OWNERSHIP AND INVESTMENT INTERESTS IN*
 2 *WHOLE HOSPITALS.—*

3 (A) *IN GENERAL.—Section 1877(d)(3) (42*
 4 *U.S.C. 1395nn(d)(3)) is amended—*

5 (i) *by striking “and” at the end of sub-*
 6 *paragraph (A); and*

7 (ii) *by redesignating subparagraph (B)*
 8 *as subparagraph (C) and inserting after*
 9 *subparagraph (A) the following:*

10 *“(B) the hospital is not a specialty hospital*
 11 *(as defined in subsection (h)(7)); and”.*

12 (B) *DEFINITION.—Section 1877(h) (42*
 13 *U.S.C. 1395nn(h)) is amended by adding at the*
 14 *end the following:*

15 “(7) *SPECIALTY HOSPITAL.—*

16 (A) *IN GENERAL.—For purposes of this*
 17 *section, except as provided in subparagraph (B),*
 18 *the term ‘specialty hospital’ means a hospital*
 19 *that is primarily or exclusively engaged in the*
 20 *care and treatment of one of the following:*

21 “(i) *patients with a cardiac condition;*

22 “(ii) *patients with an orthopedic con-*
 23 *dition;*

24 “(iii) *patients receiving a surgical pro-*
 25 *cedure; or*

1 “(iv) any other specialized category of
 2 patients or cases that the Secretary des-
 3 ignates as inconsistent with the purpose of
 4 permitting physician ownership and invest-
 5 ment interests in a hospital under this sec-
 6 tion.

7 “(B) *EXCEPTION*.—For purposes of this sec-
 8 tion, the term ‘specialty hospital’ does not in-
 9 clude any hospital—

10 “(i) determined by the Secretary—

11 “(I) to be in operation before
 12 June 12, 2003; or

13 “(II) under development as of
 14 such date;

15 “(ii) for which the number of beds and
 16 the number of physician investors at any
 17 time on or after such date is no greater
 18 than the number of such beds or investors as
 19 of such date; and

20 “(iii) that meets such other require-
 21 ments as the Secretary may specify.”.

22 (2) *OWNERSHIP AND INVESTMENT INTERESTS IN*
 23 *A RURAL PROVIDER*.—Section 1877(d)(2) (42 U.S.C.
 24 1395nn(d)(2)) is amended to read as follows:

1 “(2) *RURAL PROVIDERS.*—*In the case of des-*
 2 *ignated health services furnished in a rural area (as*
 3 *defined in section 1886(d)(2)(D)) by an entity, if—*

4 “(A) *substantially all of the designated*
 5 *health services furnished by the entity are fur-*
 6 *nished to individuals residing in such a rural*
 7 *area;*

8 “(B) *the entity is not a specialty hospital*
 9 *(as defined in subsection (h)(7)); and*

10 “(C) *the Secretary determines, with respect*
 11 *to such entity, that such services would not be*
 12 *available in such area but for the ownership or*
 13 *investment interest.”.*

14 (b) *EFFECTIVE DATE.*—*Subject to paragraph (2), the*
 15 *amendments made by this section shall apply to referrals*
 16 *made for designated health services on or after January 1,*
 17 *2004.*

18 (c) *APPLICATION OF EXCEPTION FOR HOSPITALS*
 19 *UNDER DEVELOPMENT.*—*For purposes of section*
 20 *1877(h)(7)(B)(i)(II) of the Social Security Act, as added*
 21 *by subsection (a)(1)(B), in determining whether a hospital*
 22 *is under development as of June 12, 2003, the Secretary*
 23 *shall consider—*

24 (1) *whether architectural plans have been com-*
 25 *pleted, funding has been received, zoning requirements*

1 *have been met, and necessary approvals from appro-*
 2 *prate State agencies have been received; and*

3 *(2) any other evidence the Secretary determines*
 4 *would indicate whether a hospital is under develop-*
 5 *ment as of such date.*

6 **SEC. 454. DEMONSTRATION PROGRAM FOR SUBSTITUTE**
 7 **ADULT DAY SERVICES.**

8 *(a) ESTABLISHMENT.—The Secretary shall establish a*
 9 *demonstration program (in this section referred to as the*
 10 *“demonstration program”) under which the Secretary pro-*
 11 *vides eligible medicare beneficiaries with coverage under the*
 12 *medicare program of substitute adult day services furnished*
 13 *by an adult day services facility.*

14 *(b) PAYMENT RATE FOR SUBSTITUTE ADULT DAY*
 15 *SERVICES.—*

16 *(1) PAYMENT RATE.—For purposes of making*
 17 *payments to an adult day services facility for sub-*
 18 *stitute adult day services under the demonstration*
 19 *program, the following rules shall apply:*

20 *(A) ESTIMATION OF PAYMENT AMOUNT.—*

21 *The Secretary shall estimate the amount that*
 22 *would otherwise be payable to a home health*
 23 *agency under section 1895 of the Social Security*
 24 *Act (42 U.S.C. 1395fff) for all home health serv-*

1 ices described in subsection (i)(4)(B)(i) under the
2 plan of care.

3 (B) AMOUNT OF PAYMENT.—Subject to
4 paragraph (3)(B), the total amount payable for
5 substitute adult day services under the plan of
6 care is equal to 95 percent of the amount esti-
7 mated to be payable under subparagraph (A).

8 (2) LIMITATION ON BALANCE BILLING.—Under
9 the demonstration program, an adult day services fa-
10 cility shall accept as payment in full for substitute
11 adult day services (including those services described
12 in clauses (ii) through (iv) of subsection (i)(4)(B))
13 furnished by the facility to an eligible medicare bene-
14 ficiary the amount of payment provided under the
15 demonstration program for home health services con-
16 sisting of substitute adult services.

17 (3) ADJUSTMENT IN CASE OF OVERUTILIZATION
18 OF SUBSTITUTE ADULT DAY SERVICES TO ENSURE
19 BUDGET NEUTRALITY.—The Secretary shall monitor
20 the expenditures under the demonstration program
21 and under title XVIII of the Social Security Act for
22 home health services. If the Secretary estimates that
23 the total expenditures under the demonstration pro-
24 gram and under such title XVIII for home health
25 services for a period determined by the Secretary ex-

1 *ceed expenditures that would have been made under*
 2 *such title XVIII for home health services for such pe-*
 3 *riod if the demonstration program had not been con-*
 4 *ducted, the Secretary shall adjust the rate of payment*
 5 *to adult day services facilities under paragraph*
 6 *(1)(B) in order to eliminate such excess.*

7 *(c) DEMONSTRATION PROGRAM SITES.—The dem-*
 8 *onstration program shall be conducted in not more than*
 9 *3 sites selected by the Secretary.*

10 *(d) DURATION; IMPLEMENTATION.—*

11 *(1) DURATION.—The Secretary shall conduct the*
 12 *demonstration program for a period of 3 years.*

13 *(2) IMPLEMENTATION.—The Secretary may not*
 14 *implement the demonstration program before October*
 15 *1, 2004.*

16 *(e) VOLUNTARY PARTICIPATION.—Participation of eli-*
 17 *gible medicare beneficiaries in the demonstration program*
 18 *shall be voluntary.*

19 *(f) WAIVER AUTHORITY.—*

20 *(1) IN GENERAL.—Except as provided in para-*
 21 *graph (2), the Secretary may waive such require-*
 22 *ments of titles XI and XVIII of the Social Security*
 23 *Act (42 U.S.C. 1301 et seq.; 1395 et seq.) as may be*
 24 *necessary for the purposes of carrying out the dem-*
 25 *onstration program.*

1 (2) *MAY NOT WAIVE ELIGIBILITY REQUIREMENTS*
2 *FOR HOME HEALTH SERVICES.*—*The Secretary may*
3 *not waive the beneficiary eligibility requirements for*
4 *home health services under title XVIII of the Social*
5 *Security Act.*

6 (g) *EVALUATION AND REPORT.*—

7 (1) *EVALUATION.*—*The Secretary shall conduct*
8 *an evaluation of the clinical and cost effectiveness of*
9 *the demonstration program.*

10 (2) *REPORT.*—*Not later than 30 months after the*
11 *commencement of the demonstration program, the*
12 *Secretary shall submit to Congress a report on the*
13 *evaluation conducted under paragraph (1) and shall*
14 *include in the report the following:*

15 (A) *An analysis of the patient outcomes and*
16 *costs of furnishing care to the eligible medicare*
17 *beneficiaries participating in the demonstration*
18 *program as compared to such outcomes and costs*
19 *to such beneficiaries receiving only home health*
20 *services under title XVIII of the Social Security*
21 *Act for the same health conditions.*

22 (B) *Such recommendations regarding the*
23 *extension, expansion, or termination of the pro-*
24 *gram as the Secretary determines appropriate.*

25 (i) *DEFINITIONS.*—*In this section:*

(1) *ADULT DAY SERVICES FACILITY.*—

(A) *IN GENERAL.*—*Except as provided in subparagraphs (B) and (C), the term “adult day services facility” means a public agency or private organization, or a subdivision of such an agency or organization, that—*

(i) *is engaged in providing skilled nursing services and other therapeutic services directly or under arrangement with a home health agency;*

(ii) *provides the items and services described in paragraph (4)(B); and*

(iii) *meets the requirements of paragraphs (2) through (8) of subsection (o).*

(B) *INCLUSION.*—*Notwithstanding subparagraph (A), the term “adult day services facility” shall include a home health agency in which the items and services described in clauses (ii) through (iv) of paragraph (4)(B) are provided—*

(i) *by an adult day services program that is licensed or certified by a State, or accredited, to furnish such items and services in the State; and*

(ii) *under arrangements with that program made by such agency.*

1 (C) *WAIVER OF SURETY BOND.*—*The Sec-*
 2 *retary may waive the requirement of a surety*
 3 *bond under section 1861(o)(7) of the Social Secu-*
 4 *rity Act (42 U.S.C. 1395x(o)(7)) in the case of*
 5 *an agency or organization that provides a com-*
 6 *parable surety bond under State law.*

7 (2) *ELIGIBLE MEDICARE BENEFICIARY.*—*The*
 8 *term “eligible medicare beneficiary” means an indi-*
 9 *vidual eligible for home health services under title*
 10 *XVIII of the Social Security Act.*

11 (3) *HOME HEALTH AGENCY.*—*The term “home*
 12 *health agency” has the meaning given such term in*
 13 *section 1861(o) of the Social Security Act (42 U.S.C.*
 14 *1395x(o)).*

15 (4) *SUBSTITUTE ADULT DAY SERVICES.*—

16 (A) *IN GENERAL.*—*The term “substitute*
 17 *adult day services” means the items and services*
 18 *described in subparagraph (B) that are fur-*
 19 *nished to an individual by an adult day services*
 20 *facility as a part of a plan under section*
 21 *1861(m) of the Social Security Act (42 U.S.C.*
 22 *1395x(m)) that substitutes such services for some*
 23 *or all of the items and services described in sub-*
 24 *paragraph (B)(i) furnished by a home health*

1 *agency under the plan, as determined by the*
 2 *physician establishing the plan.*

3 *(B) ITEMS AND SERVICES DESCRIBED.—The*
 4 *items and services described in this subpara-*
 5 *graph are the following items and services:*

6 *(i) Items and services described in*
 7 *paragraphs (1) through (7) of such section*
 8 *1861(m).*

9 *(ii) Meals.*

10 *(iii) A program of supervised activities*
 11 *designed to promote physical and mental*
 12 *health and furnished to the individual by*
 13 *the adult day services facility in a group*
 14 *setting for a period of not fewer than 4 and*
 15 *not greater than 12 hours per day.*

16 *(iv) A medication management pro-*
 17 *gram (as defined in subparagraph (C)).*

18 *(C) MEDICATION MANAGEMENT PROGRAM.—*
 19 *For purposes of subparagraph (B)(iv), the term*
 20 *“medication management program” means a*
 21 *program of services, including medicine screen-*
 22 *ing and patient and health care provider edu-*
 23 *cation programs, that provides services to*
 24 *minimize—*

- 1 (i) unnecessary or inappropriate use of
 2 prescription drugs; and
 3 (ii) adverse events due to unintended
 4 prescription drug-to-drug interactions.

5 **SEC. 455. MEDPAC STUDY ON MEDICARE PAYMENTS AND**
 6 **EFFICIENCIES IN THE HEALTH CARE SYSTEM.**

7 Not later than 18 months after the date of enactment
 8 of this Act, the Medicare Payment Advisory Commission
 9 established under section 1805 of the Social Security Act
 10 (42 U.S.C. 1395b–6) shall provide Congress with rec-
 11 ommendations to recognize and reward, within payment
 12 methodologies for physicians and hospitals established
 13 under the medicare program under title XVIII of the Social
 14 Security Act, efficiencies, and the lower utilization of serv-
 15 ices created by the practice of medicine in historically effi-
 16 cient and low-cost areas. Measures of efficiency recognized
 17 in accordance with the preceding sentence shall include—

- 18 (1) shorter hospital stays than the national aver-
 19 age;
 20 (2) fewer physician visits than the national av-
 21 erage;
 22 (3) fewer laboratory tests than the national aver-
 23 age;
 24 (4) a greater utilization of hospice services than
 25 the national average; and

1 (5) *the efficacy of disease management and pre-*
 2 *ventive health services.*

3 **SEC. 456. MEDICARE COVERAGE OF KIDNEY DISEASE EDU-**
 4 **CATION SERVICES.**

5 (a) *COVERAGE OF KIDNEY DISEASE EDUCATION*
 6 *SERVICES.—*

7 (1) *IN GENERAL.—Section 1861 of the Social Se-*
 8 *curity Act (42 U.S.C.1395x) is amended—*

9 (A) *in subsection (s)(2)—*

10 (i) *in subparagraph (U), by striking*
 11 *“and” at the end;*

12 (ii) *in subparagraph (V)(iii), by add-*
 13 *ing “and” at the end; and*

14 (iii) *by adding at the end the following*
 15 *new subparagraph:*

16 “(W) *kidney disease education services (as de-*
 17 *finied in subsection (ww));”;* and

18 (B) *by adding at the end the following new*
 19 *subsection:*

20 “*Kidney Disease Education Services*

21 “(ww)(1) *The term ‘kidney disease education services’*
 22 *means educational services that are—*

23 “(A) *furnished to an individual with kidney dis-*
 24 *ease who, according to accepted clinical guidelines*

1 *identified by the Secretary, will require dialysis or a*
 2 *kidney transplant;*

3 “(B) *furnished, upon the referral of the physi-*
 4 *cian managing the individual’s kidney condition, by*
 5 *a qualified person (as defined in paragraph (2)); and*

6 “(C) *designed—*

7 “(i) *to provide comprehensive information*
 8 *regarding—*

9 “(I) *the management of comorbidities;*

10 “(II) *the prevention of uremic com-*
 11 *plications; and*

12 “(III) *each option for renal replace-*
 13 *ment therapy (including peritoneal dialysis,*
 14 *hemodialysis (including vascular access op-*
 15 *tions), and transplantation); and*

16 “(ii) *to ensure that the individual has the*
 17 *opportunity to actively participate in the choice*
 18 *of therapy.*

19 “(2) *The term ‘qualified person’ means—*

20 “(A) *a physician (as described in subsection*
 21 *(r)(1));*

22 “(B) *an individual who—*

23 “(i) *is—*

24 “(I) *a registered nurse;*

1 “(II) a registered dietitian or nutrition
2 professional (as defined in subsection
3 (vv)(2));

4 “(III) a clinical social worker (as de-
5 fined in subsection (hh)(1));

6 “(IV) a physician assistant, nurse
7 practitioner, or clinical nurse specialist (as
8 those terms are defined in subsection
9 (aa)(5)); or

10 “(V) a transplant coordinator; and

11 “(ii) meets such requirements related to ex-
12 perience and other qualifications that the Sec-
13 retary finds necessary and appropriate for fur-
14 nishing the services described in paragraph (1);
15 or

16 “(C) a renal dialysis facility subject to the re-
17 quirements of section 1881(b)(1) with personnel
18 who—

19 “(i) provide the services described in para-
20 graph (1); and

21 “(ii) meet the requirements of subparagraph
22 (A) or (B).

23 “(3) The Secretary shall develop the requirements
24 under paragraph (2)(B)(ii) after consulting with physi-
25 cians, health educators, professional organizations, accred-

1 iting organizations, kidney patient organizations, dialysis
 2 facilities, transplant centers, network organizations de-
 3 scribed in section 1881(c)(2), and other knowledgeable per-
 4 sons.

5 “(4) In promulgating regulations to carry out this sub-
 6 section, the Secretary shall ensure that such regulations en-
 7 sure that each beneficiary who is entitled to kidney disease
 8 education services under this title receives such services in
 9 a timely manner that ensures that the beneficiary receives
 10 the maximum benefit of those services.

11 “(5) The Secretary shall monitor the implementation
 12 of this subsection to ensure that beneficiaries who are eligi-
 13 ble for kidney disease education services receive such serv-
 14 ices in the manner described in paragraph (4).”.

15 (2) *PAYMENT UNDER PHYSICIAN FEE SCHED-*
 16 *ULE.*—Section 1848(j)(3) of such Act (42 U.S.C.
 17 1395w-4(j)(3)) is amended by inserting “, (2)(W)”,
 18 after “(2)(S)”.

19 (3) *PAYMENT TO RENAL DIALYSIS FACILITIES.*—
 20 Section 1881(b) of such Act (42 U.S.C. 1395rr(b)), as
 21 amended by section 433(b)(5), is further amended by
 22 adding at the end the following new paragraph:

23 “(13) For purposes of paragraph (7), the single
 24 composite weighted formulas determined under such
 25 paragraph shall not take into account the amount of

1 *payment for kidney disease education services (as de-*
 2 *finied in section 1861(ww)). Instead, payment for such*
 3 *services shall be made to the renal dialysis facility on*
 4 *an assignment-related basis under section 1848.”.*

5 (4) *ANNUAL REPORT TO CONGRESS.—Not later*
 6 *than April 1, 2004, and annually thereafter, the Sec-*
 7 *retary of Health and Human Services shall submit to*
 8 *Congress a report on the number of medicare bene-*
 9 *ficiaries who are entitled to kidney disease education*
 10 *services (as defined in section 1861(ww) of the Social*
 11 *Security Act, as added by paragraph (1)) under title*
 12 *XVIII of such Act and who receive such services, to-*
 13 *gether with such recommendations for legislative and*
 14 *administrative action as the Secretary determines to*
 15 *be appropriate to fulfill the legislative intent that re-*
 16 *sulted in the enactment of that subsection.*

17 (b) *EFFECTIVE DATE.—The amendments made by this*
 18 *section shall apply to services furnished on or after January*
 19 *1, 2004.*

20 **SEC. 457. FRONTIER EXTENDED STAY CLINIC DEMONSTRA-**
 21 **TION PROJECT.**

22 (a) *AUTHORITY TO CONDUCT DEMONSTRATION*
 23 *PROJECT.—The Secretary shall waive such provisions of the*
 24 *medicare program established under title XVIII of the So-*
 25 *cial Security Act (42 U.S.C. 1395 et seq.) as are necessary*

1 *to conduct a demonstration project under which frontier ex-*
2 *tended stay clinics described in subsection (b) in isolated*
3 *rural areas are treated as providers of items and services*
4 *under the medicare program.*

5 (b) *CLINICS DESCRIBED.—A frontier extended stay*
6 *clinic is described in this subsection if the clinic—*

7 (1) *is located in a community where the closest*
8 *short-term acute care hospital or critical access hos-*
9 *pital is at least 75 miles away from the community*
10 *or is inaccessible by public road; and*

11 (2) *is designed to address the needs of—*

12 (A) *seriously or critically ill or injured pa-*
13 *tients who, due to adverse weather conditions or*
14 *other reasons, cannot be transferred quickly to*
15 *acute care referral centers; or*

16 (B) *patients who need monitoring and ob-*
17 *servation for a limited period of time.*

18 (c) *DEFINITIONS.—In this section, the terms “hos-*
19 *pital” and “critical access hospital” have the meanings*
20 *given such terms in subsections (e) and (mm), respectively,*
21 *of section 1861 of the Social Security Act (42 U.S.C.*
22 *1395x).*

1 **SEC. 458. IMPROVEMENTS IN NATIONAL COVERAGE DETER-**
 2 **MINATION PROCESS TO RESPOND TO**
 3 **CHANGES IN TECHNOLOGY.**

4 (a) *IN GENERAL.*—Section 1862 (42 U.S.C. 1395y) is
 5 amended—

6 (A) *in the third sentence of subsection (a)*
 7 *by inserting “consistent with subsection (j)”*
 8 *after “the Secretary shall ensure”; and*

9 (B) *by adding at the end the following new*
 10 *subsection:*

11 “(j) *NATIONAL COVERAGE DETERMINATION PROC-*
 12 *ESS.*—

13 “(1) *TIMEFRAME FOR DECISIONS ON REQUESTS*
 14 *FOR NATIONAL COVERAGE DETERMINATIONS.*—*In the*
 15 *case of a request for a national coverage determina-*
 16 *tion that—*

17 “(A) *does not require a technology assess-*
 18 *ment from an outside entity or deliberation from*
 19 *the Medicare Coverage Advisory Committee, the*
 20 *decision on the request shall be made not later*
 21 *than 6 months after the date of the request; or*

22 “(B) *requires such an assessment or delib-*
 23 *eration and in which a clinical trial is not re-*
 24 *quested, the decision on the request shall be made*
 25 *not later than 9 months after the date of the re-*
 26 *quest.*

1 “(2) *PROCESS FOR PUBLIC COMMENT IN NA-*
 2 *TIONAL COVERAGE DETERMINATIONS.*—*At the end of*
 3 *the 6-month period (with respect to a request under*
 4 *paragraph (1)(A)) or 9-month period (with respect to*
 5 *a request under paragraph (1)(B)) that begins on the*
 6 *date a request for a national coverage determination*
 7 *is made, the Secretary shall—*

8 “(A) *make a draft of proposed decision on*
 9 *the request available to the public through the*
 10 *Medicare Internet site of the Department of*
 11 *Health and Human Services or other appro-*
 12 *priate means;*

13 “(B) *provide a 30-day period for public*
 14 *comment on such draft;*

15 “(C) *make a final decision on the request*
 16 *within 60 days of the conclusion of the 30-day*
 17 *period referred to under subparagraph (B);*

18 “(D) *include in such final decision sum-*
 19 *maries of the public comments received and re-*
 20 *sponses thereto;*

21 “(E) *make available to the public the clin-*
 22 *ical evidence and other data used in making*
 23 *such a decision when the decision differs from*
 24 *the recommendations of the Medicare Coverage*
 25 *Advisory Committee; and*

1 “(F) in the case of a decision to grant the
 2 coverage determination, assign a temporary or
 3 permanent code and implement the coverage de-
 4 cision at the end of the 60-day period referred to
 5 in subparagraph (C).

6 “(3) NATIONAL COVERAGE DETERMINATION DE-
 7 FINED.—For purposes of this subsection, the term ‘na-
 8 tional coverage determination’ has the meaning given
 9 such term in section 1869(f)(1)(B).”.

10 (b) EFFECTIVE DATE.—The amendments made by this
 11 section shall apply to national coverage determinations as
 12 of January 1, 2004.

13 **SEC. 459. INCREASE IN MEDICARE PAYMENT FOR CERTAIN**
 14 **HOME HEALTH SERVICES.**

15 (a) IN GENERAL.—Section 1895 of the Social Security
 16 Act (42 U.S.C. 1395fff) is amended by adding at the end
 17 the following:

18 “(f) INCREASE IN PAYMENT FOR SERVICES FUR-
 19 NISHED IN A RURAL AREA.—

20 “(1) IN GENERAL.—In the case of home health
 21 services furnished in a rural area (as defined in sec-
 22 tion 1886(d)(2)(D)) on or after October 1, 2004 and
 23 before October 1, 2006, the Secretary shall increase
 24 the payment amount otherwise made under this sec-
 25 tion for such services by 10 percent.

1 “(2) *WAIVER OF BUDGET NEUTRALITY.*—*The*
 2 *Secretary shall not reduce the standard prospective*
 3 *payment amount (or amounts) under this section ap-*
 4 *plicable to home health services furnished during any*
 5 *period to offset the increase in payments resulting*
 6 *from the application of paragraph (1).”.*

7 *(b) PAYMENT ADJUSTMENT.*—*Section 1895(b)(5) of the*
 8 *Social Security Act (42 U.S.C. 1395fff(b)(5)) is amended*
 9 *by adding at the end the following: “Notwithstanding this*
 10 *paragraph, the total amount of the additional payments or*
 11 *payment adjustments made under this paragraph may not*
 12 *exceed, with respect to fiscal year 2004, 3 percent, and, with*
 13 *respect to fiscal years 2005 and 2006, 4 percent, of the total*
 14 *payments projected or estimated to be made based on the*
 15 *prospective payment system under this subsection in the*
 16 *year involved.”.*

17 *(c) EFFECTIVE DATE.*—*The amendments made by this*
 18 *section shall apply to services furnished on or after October*
 19 *1, 2003.*

20 **SEC. 460. FRONTIER EXTENDED STAY CLINIC DEMONSTRA-**
 21 **TION PROJECT.**

22 *(a) AUTHORITY TO CONDUCT DEMONSTRATION*
 23 *PROJECT.*—*The Secretary shall waive such provisions of the*
 24 *medicare program established under title XVIII of the So-*
 25 *cial Security Act (42 U.S.C. 1395 et seq.) as are necessary*

1 *to conduct a demonstration project under which frontier ex-*
 2 *tended stay clinics described in subsection (b) in isolated*
 3 *rural areas are treated as providers of items and services*
 4 *under the medicare program.*

5 (b) *CLINICS DESCRIBED.—A frontier extended stay*
 6 *clinic is described in this subsection if the clinic—*

7 (1) *is located in a community where the closest*
 8 *short-term acute care hospital or critical access hos-*
 9 *pital is at least 75 miles away from the community*
 10 *or is inaccessible by public road; and*

11 (2) *is designed to address the needs of—*

12 (A) *seriously or critically ill or injured pa-*
 13 *tients who, due to adverse weather conditions or*
 14 *other reasons, cannot be transferred quickly to*
 15 *acute care referral centers; or*

16 (B) *patients who need monitoring and ob-*
 17 *servation for a limited period of time.*

18 (c) *DEFINITIONS.—In this section, the terms “hos-*
 19 *pital” and “critical access hospital” have the meanings*
 20 *given such terms in subsections (e) and (mm), respectively,*
 21 *of section 1861 of the Social Security Act (42 U.S.C.*
 22 *1395x).*

1 **SEC. 461. MEDICARE SECONDARY PAYOR (MSP) PROVI-**
 2 **SIONS.**

3 (a) *TECHNICAL AMENDMENT CONCERNING SEC-*
 4 *RETARY'S AUTHORITY TO MAKE CONDITIONAL PAYMENT*
 5 *WHEN CERTAIN PRIMARY PLANS DO NOT PAY PROMPT-*
 6 *LY.—*

7 (1) *IN GENERAL.—Section 1862(b)(2) (42 U.S.C.*
 8 *1395y(b)(2)) is amended—*

9 (A) *in subparagraph (A)(ii), by striking*
 10 *“promptly (as determined in accordance with*
 11 *regulations)”;*

12 (B) *in subparagraph (B)—*

13 (i) *by redesignating clauses (i) through*
 14 *(iii) as clauses (ii) through (iv), respec-*
 15 *tively; and*

16 (ii) *by inserting before clause (ii), as*
 17 *so redesignated, the following new clause:*

18 “(i) *AUTHORITY TO MAKE CONDI-*
 19 *TIONAL PAYMENT.—The Secretary may*
 20 *make payment under this title with respect*
 21 *to an item or service if a primary plan de-*
 22 *scribed in subparagraph (A)(ii) has not*
 23 *made or cannot reasonably be expected to*
 24 *make payment with respect to such item or*
 25 *service promptly (as determined in accord-*
 26 *ance with regulations). Any such payment*

1 *by the Secretary shall be conditioned on re-*
 2 *imbursement to the appropriate Trust Fund*
 3 *in accordance with the succeeding provi-*
 4 *sions of this subsection.”.*

5 (2) *EFFECTIVE DATE.*—*The amendments made*
 6 *by paragraph (1) shall be effective as if included in*
 7 *the enactment of title III of the Medicare and Med-*
 8 *icaid Budget Reconciliation Amendments of 1984*
 9 *(Public Law 98-369).*

10 (b) *CLARIFYING AMENDMENTS TO CONDITIONAL PAY-*
 11 *MENT PROVISIONS.*—*Section 1862(b)(2) (42 U.S.C.*
 12 *1395y(b)(2)) is further amended—*

13 (1) *in subparagraph (A), in the matter following*
 14 *clause (ii), by inserting the following sentence at the*
 15 *end: “An entity that engages in a business, trade, or*
 16 *profession shall be deemed to have a self-insured plan*
 17 *if it carries its own risk (whether by a failure to ob-*
 18 *tain insurance, or otherwise) in whole or in part.”;*

19 (2) *in subparagraph (B)(ii), as redesignated by*
 20 *subsection (a)(2)(B)—*

21 (A) *by striking the first sentence and insert-*
 22 *ing the following: “A primary plan, and an enti-*
 23 *ty that receives payment from a primary plan,*
 24 *shall reimburse the appropriate Trust Fund for*
 25 *any payment made by the Secretary under this*

1 *title with respect to an item or service if it is*
 2 *demonstrated that such primary plan has or had*
 3 *a responsibility to make payment with respect to*
 4 *such item or service. A primary plan’s responsi-*
 5 *bility for such payment may be demonstrated by*
 6 *a judgment, a payment conditioned upon the re-*
 7 *cipient’s compromise, waiver, or release (whether*
 8 *or not there is a determination or admission of*
 9 *liability) of payment for items or services in-*
 10 *cluded in a claim against the primary plan or*
 11 *the primary plan’s insured, or by other means.”;*
 12 *and*

13 *(B) in the final sentence, by striking “on*
 14 *the date such notice or other information is re-*
 15 *ceived” and inserting “on the date notice of, or*
 16 *information related to, a primary plan’s respon-*
 17 *sibility for such payment or other information is*
 18 *received”;* *and*

19 *(3) in subparagraph (B)(iii), , as redesignated*
 20 *by subsection (a)(2)(B), by striking the first sentence*
 21 *and inserting the following: “In order to recover pay-*
 22 *ment made under this title for an item or service, the*
 23 *United States may bring an action against any or all*
 24 *entities that are or were required or responsible (di-*
 25 *rectly, as an insurer or self-insurer, as a third-party*

1 administrator, as an employer that sponsors or con-
 2 tributes to a group health plan, or large group health
 3 plan, or otherwise) to make payment with respect to
 4 the same item or service (or any portion thereof)
 5 under a primary plan. The United States may, in ac-
 6 cordance with paragraph (3)(A) collect double dam-
 7 ages against any such entity. In addition, the United
 8 States may recover under this clause from any entity
 9 that has received payment from a primary plan or
 10 from the proceeds of a primary plan's payment to
 11 any entity.”.

12 (c) CLERICAL AMENDMENTS.—Section 1862(b) (42
 13 U.S.C. 1395y(b)) is amended—

14 (1) in paragraph (1)(A), by moving the indenta-
 15 tion of clauses (ii) through (v) 2 ems to the left; and

16 (2) in paragraph (3)(A), by striking “such” be-
 17 fore “paragraphs”.

18 **SEC. 462. MEDICARE PANCREATIC ISLET CELL TRANSPLANT**

19 **DEMONSTRATION PROJECT.**

20 (a) ESTABLISHMENT.—In order to test the appro-
 21 priateness of pancreatic islet cell transplantation, not later
 22 than 120 days after the date of the enactment of this Act,
 23 the Secretary shall establish a demonstration project which
 24 the Secretary, provides for payment under the medicare
 25 program under title XVIII of the Social Security Act for

1 *pancreatic islet cell transplantation and related items and*
 2 *services in the case of medicare beneficiaries who have type*
 3 *I (juvenile) diabetes and have end stage renal disease.*

4 *(b) DURATION OF PROJECT.—The authority of the Sec-*
 5 *retary to conduct the demonstration project under this sec-*
 6 *tion shall terminate on the date that is 5 years after the*
 7 *date of the establishment of the project.*

8 *(c) EVALUATION AND REPORT.—The Secretary shall*
 9 *conduct an evaluation of the outcomes of the demonstration*
 10 *project. Not later than 120 days after the date of the termi-*
 11 *nation of the demonstration project under subsection (b),*
 12 *the Secretary shall submit to Congress a report on the*
 13 *project, including recommendations for such legislative and*
 14 *administrative action as the Secretary deems appropriate.*

15 *(d) PAYMENT METHODOLOGY.—The Secretary shall es-*
 16 *tablish an appropriate payment methodology for the provi-*
 17 *sion of items and services under the demonstration project,*
 18 *which may include a payment methodology that bundles,*
 19 *to the maximum extent feasible, payment for all such items*
 20 *and services.*

21 **SEC. 463. INCREASE IN MEDICARE PAYMENT FOR CERTAIN**
 22 **HOME HEALTH SERVICES.**

23 *(a) IN GENERAL.—Section 1895 of the Social Security*
 24 *Act (42 U.S.C. 1395fff) is amended by adding at the end*
 25 *the following:*

1 “(f) *INCREASE IN PAYMENT FOR SERVICES FUR-*
 2 *NISHED IN A RURAL AREA.*—

3 “(1) *IN GENERAL.*—*In the case of home health*
 4 *services furnished in a rural area (as defined in sec-*
 5 *tion 1886(d)(2)(D)) on or after October 1, 2004, and*
 6 *before October 1, 2006, the Secretary shall increase*
 7 *the payment amount otherwise made under this sec-*
 8 *tion for such services by 10 percent.*

9 “(2) *WAIVER OF BUDGET NEUTRALITY.*—*The*
 10 *Secretary shall not reduce the standard prospective*
 11 *payment amount (or amounts) under this section ap-*
 12 *plicable to home health services furnished during any*
 13 *period to offset the increase in payments resulting*
 14 *from the application of paragraph (1).”.*

15 (b) *PAYMENT ADJUSTMENT.*—*Section 1895(b)(5) of the*
 16 *Social Security Act (42 U.S. C. 1395fff(b)(5)) is amended*
 17 *by adding at the end the following: “Notwithstanding this*
 18 *paragraph, the total amount of the additional payments or*
 19 *payment adjustments made under this paragraph may not*
 20 *exceed, with respect to fiscal year 2004, 3 percent, and, with*
 21 *respect to fiscal years 2005 and 2006, 4 percent, of the total*
 22 *payments projected or estimated to be made based on the*
 23 *prospective payment system under this subsection in the*
 24 *year involved.”.*

1 (c) *EFFECTIVE DATE.*—*The amendments made by this*
2 *section shall apply to services furnished on or after October*
3 *1, 2003.*

4 **SEC. 464. SENSE OF THE SENATE CONCERNING MEDICARE**
5 **PAYMENT UPDATE FOR PHYSICIANS AND**
6 **OTHER HEALTH PROFESSIONALS.**

7 (a) *FINDINGS.*—*The Senate makes the following find-*
8 *ings:*

9 (1) *The formula by which medicare payments*
10 *are updated each year for services furnished by physi-*
11 *cians and other health professionals is fundamentally*
12 *flawed.*

13 (2) *The flawed physician payment update for-*
14 *mula is causing a continuing physician payment cri-*
15 *sis, and, without congressional action, medicare pay-*
16 *ment rates for physicians and other practitioners are*
17 *predicted to fall by 4.2 percent in 2004.*

18 (3) *A physician payment cut in 2004 would the*
19 *fifth cut since 1991, and would be on top of a 5.4 per-*
20 *cent cut in 2002, with additional cuts estimated for*
21 *2005, 2006, and 2007. From 1991 through 2003, pay-*
22 *ment rates for physicians and health professionals fell*
23 *14 percent behind practice cost inflation as measured*
24 *by medicare's own conservative estimates.*

1 (4) *The sustainable growth rate (SGR) expendi-*
 2 *ture target, which is the basis for the physician pay-*
 3 *ment update, is linked to the gross domestic product*
 4 *and penalizes physicians and other practitioners for*
 5 *volume increases that they cannot control and that*
 6 *the government actively promotes through new cov-*
 7 *erage decisions, quality improvement activities, and*
 8 *other initiatives that, while beneficial to patients, are*
 9 *not reflected in the SGR.*

10 (b) *SENSE OF THE SENATE.—It is the sense of the Sen-*
 11 *ate that medicare beneficiary access to quality care may*
 12 *be compromised if Congress does not take action to prevent*
 13 *cuts in 2004 and the following years that result from the*
 14 *SGR formula.*

15 **TITLE V—MEDICARE APPEALS,**
 16 **REGULATORY, AND CON-**
 17 **TRACTING IMPROVEMENTS**
 18 **Subtitle A—Regulatory Reform**

19 **SEC. 501. RULES FOR THE PUBLICATION OF A FINAL REGU-**
 20 **LATION BASED ON THE PREVIOUS PUBLICA-**
 21 **TION OF AN INTERIM FINAL REGULATION.**

22 (a) *IN GENERAL.—Section 1871(a) (42 U.S.C.*
 23 *1395hh(a)) is amended by adding at the end the following*
 24 *new paragraph:*

1 “(3)(A) *With respect to the publication of a final regu-*
2 *lation based on the previous publication of an interim final*
3 *regulation—*

4 “(i) *subject to subparagraph (B), the Secretary*
5 *shall publish the final regulation within the 12-month*
6 *period that begins on the date of publication of the*
7 *interim final regulation;*

8 “(ii) *if a final regulation is not published by the*
9 *deadline established under this paragraph, the in-*
10 *terim final regulation shall not continue in effect un-*
11 *less the Secretary publishes a notice described in sub-*
12 *paragraph (B) by such deadline; and*

13 “(iii) *the final regulation shall include responses*
14 *to comments submitted in response to the interim*
15 *final regulation.*

16 “(B) *If the Secretary determines before the deadline*
17 *otherwise established in this paragraph that there is good*
18 *cause, specified in a notice published before such deadline,*
19 *for delaying the deadline otherwise applicable under this*
20 *paragraph, the deadline otherwise established under this*
21 *paragraph shall be extended for such period (not to exceed*
22 *12 months) as the Secretary specifies in such notice.”.*

23 (b) *EFFECTIVE DATE.—The amendment made by sub-*
24 *section (a) shall take effect on the date of enactment of this*

1 *Act and shall apply to interim final regulations published*
 2 *on or after such date.*

3 (c) *STATUS OF PENDING INTERIM FINAL REGULA-*
 4 *TIONS.*—Not later than 6 months after the date of enactment
 5 of this Act, the Secretary shall publish a notice in the Fed-
 6 eral Register that provides the status of each interim final
 7 regulation that was published on or before the date of enact-
 8 ment of this Act and for which no final regulation has been
 9 published. Such notice shall include the date by which the
 10 Secretary plans to publish the final regulation that is based
 11 on the interim final regulation.

12 **SEC. 502. COMPLIANCE WITH CHANGES IN REGULATIONS**
 13 **AND POLICIES.**

14 (a) *NO RETROACTIVE APPLICATION OF SUBSTANTIVE*
 15 *CHANGES.*—

16 (1) *IN GENERAL.*—Section 1871 (42 U.S.C.
 17 1395hh) is amended by adding at the end the fol-
 18 lowing new subsection:

19 “(d)(1)(A) A substantive change in regulations, man-
 20 ual instructions, interpretative rules, statements of policy,
 21 or guidelines of general applicability under this title shall
 22 not be applied (by extrapolation or otherwise) retroactively
 23 to items and services furnished before the effective date of
 24 the change, unless the Secretary determines that—

1 “(i) such retroactive application is necessary to
2 comply with statutory requirements; or

3 “(ii) failure to apply the change retroactively
4 would be contrary to the public interest.”.

5 (2) *EFFECTIVE DATE.*—The amendment made by
6 paragraph (1) shall apply to substantive changes
7 issued on or after the date of enactment of this Act.

8 (b) *TIMELINE FOR COMPLIANCE WITH SUBSTANTIVE*
9 *CHANGES AFTER NOTICE.*—

10 (1) *IN GENERAL.*—Section 1871(d)(1), as added
11 by subsection (a), is amended by adding at the end
12 the following:

13 “(B) A compliance action may be made against a pro-
14 vider of services, physician, practitioner, or other supplier
15 with respect to noncompliance with such a substantive
16 change only for items and services furnished on or after
17 the effective date of the change.

18 “(C)(i) Except as provided in clause (ii), a substantive
19 change may not take effect before the date that is the end
20 of the 30-day period that begins on the date that the Sec-
21 retary has issued or published, as the case may be, the sub-
22 stantive change.

23 “(ii) The Secretary may provide for a substantive
24 change to take effect on a date that precedes the end of the
25 30-day period under clause (i) if the Secretary finds that

1 *waiver of such 30-day period is necessary to comply with*
 2 *statutory requirements or that the application of such 30-*
 3 *day period is contrary to the public interest. If the Sec-*
 4 *retary provides for an earlier effective date pursuant to this*
 5 *clause, the Secretary shall include in the issuance or publi-*
 6 *cation of the substantive change a finding described in the*
 7 *first sentence, and a brief statement of the reasons for such*
 8 *finding.”.*

9 (2) *EFFECTIVE DATE.*—*The amendment made by*
 10 *paragraph (1) shall apply to compliance actions un-*
 11 *dertaken on or after the date of enactment of this Act.*

12 **SEC. 503. REPORT ON LEGAL AND REGULATORY INCONSIST-**
 13 **ENCIES.**

14 *Section 1871 (42 U.S.C. 1395hh), as amended by sec-*
 15 *tion 502(a)(1), is amended by adding at the end the fol-*
 16 *lowing new subsection:*

17 “(e)(1) *Not later than 2 years after the date of enact-*
 18 *ment of this subsection, and every 3 years thereafter, the*
 19 *Secretary shall submit to Congress a report with respect*
 20 *to the administration of this title and areas of inconsistency*
 21 *or conflict among the various provisions under law and reg-*
 22 *ulation.*

23 “(2) *In preparing a report under paragraph (1), the*
 24 *Secretary shall collect—*

1 “(A) information from beneficiaries, providers of
 2 services, physicians, practitioners, and other suppliers
 3 with respect to such areas of inconsistency and con-
 4 flict; and

5 “(B) information from medicare contractors that
 6 tracks the nature of all communications and cor-
 7 respondence.

8 “(3) A report under paragraph (1) shall include a de-
 9 scription of efforts by the Secretary to reduce such inconsis-
 10 tency or conflicts, and recommendations for legislation or
 11 administrative action that the Secretary determines appro-
 12 priate to further reduce such inconsistency or conflicts.”.

13 **SEC. 504. STREAMLINING AND SIMPLIFICATION OF MEDI-**
 14 **CARE REGULATIONS.**

15 (a) *IN GENERAL.*—The Secretary of Health and
 16 Human Services shall conduct an analysis of the regula-
 17 tions issued under title XVIII of the Social Security Act
 18 and related laws in order to determine how such regulations
 19 may be streamlined and simplified to increase the efficiency
 20 and effectiveness of the medicare program without harming
 21 beneficiaries or providers and to decrease the burdens the
 22 medicare payment systems impose on both beneficiaries and
 23 providers.

24 (b) *REDUCTION IN REGULATIONS.*—The Secretary,
 25 after completion of the analysis under subsection (a), shall

1 *direct the rewriting of the regulations described in sub-*
 2 *section (a) in such a manner as to—*

3 (1) *reduce the number of words comprising all*
 4 *regulations by at least two-thirds by October 1, 2004,*
 5 *and*

6 (2) *ensure the simple, effective, and efficient op-*
 7 *eration of the medicare program.*

8 (c) *APPLICATION OF THE PAPERWORK REDUCTION*
 9 *ACT.—The Secretary shall apply the provisions of chapter*
 10 *35 of title 44, United States Code (commonly known as the*
 11 *“Paperwork Reduction Act”)* *to the provisions of this Act*
 12 *to ensure that any regulations issued to implement this Act*
 13 *are written in plain language, are streamlined, promote the*
 14 *maximum efficiency and effectiveness of the medicare and*
 15 *medicaid programs without harming beneficiaries or pro-*
 16 *viders, and minimize the burdens the payment systems af-*
 17 *fected by this Act impose on both beneficiaries and pro-*
 18 *viders.*

19 (d) *FEASIBILITY.—If the Secretary determines that the*
 20 *two-thirds reduction in words by October 1, 2004 required*
 21 *in subsection (b)(1) is not feasible, he shall inform Congress*
 22 *in writing by July 1, 2004 of the reasons for its*
 23 *unfeasibility. He shall then establish a feasible reduction*
 24 *to be achieved by January 1, 2005.*

1 ***Subtitle B—Appeals Process Reform***

2 ***SEC. 511. SUBMISSION OF PLAN FOR TRANSFER OF RE-***
3 ***SPONSIBILITY FOR MEDICARE APPEALS.***

4 *(a) SUBMISSION OF TRANSITION PLAN.—*

5 *(1) IN GENERAL.—Not later than April 1, 2004,*
6 *the Commissioner of Social Security and the Sec-*
7 *retary shall develop and transmit to Congress and the*
8 *Comptroller General of the United States a plan*
9 *under which the functions of administrative law*
10 *judges responsible for hearing cases under title XVIII*
11 *of the Social Security Act (and related provisions in*
12 *title XI of such Act) are transferred from the responsi-*
13 *bility of the Commissioner and the Social Security*
14 *Administration to the Secretary and the Department*
15 *of Health and Human Services.*

16 *(2) CONTENTS.—The plan shall include informa-*
17 *tion on the following:*

18 *(A) WORKLOAD.—The number of such ad-*
19 *ministrative law judges and support staff re-*
20 *quired now and in the future to hear and decide*
21 *such cases in a timely manner, taking into ac-*
22 *count the current and anticipated claims volume,*
23 *appeals, number of beneficiaries, and statutory*
24 *changes.*

1 (B) *COST PROJECTIONS AND FINANCING.*—
2 *Funding levels required for fiscal year 2005 and*
3 *subsequent fiscal years to carry out the functions*
4 *transferred under the plan and how such transfer*
5 *should be financed.*

6 (C) *TRANSITION TIMETABLE.*—*A timetable*
7 *for the transition.*

8 (D) *REGULATIONS.*—*The establishment of*
9 *specific regulations to govern the appeals process.*

10 (E) *CASE TRACKING.*—*The development of a*
11 *unified case tracking system that will facilitate*
12 *the maintenance and transfer of case specific*
13 *data across both the fee-for-service and managed*
14 *care components of the medicare program.*

15 (F) *FEASIBILITY OF PRECEDENTIAL AU-*
16 *THORITY.*—*The feasibility of developing a proc-*
17 *ess to give decisions of the Departmental Appeals*
18 *Board in the Department of Health and Human*
19 *Services addressing broad legal issues binding,*
20 *precedential authority.*

21 (G) *ACCESS TO ADMINISTRATIVE LAW*
22 *JUDGES.*—*The feasibility of—*

23 (i) *filing appeals with administrative*
24 *law judges electronically; and*

1 (ii) conducting hearings using tele- or
2 video-conference technologies.

3 (H) *INDEPENDENCE OF ADMINISTRATIVE*
4 *LAW JUDGES.*—*The steps that should be taken to*
5 *ensure the independence of administrative law*
6 *judges, including ensuring that such judges are*
7 *in an office that is functionally and operation-*
8 *ally separate from the Centers for Medicare &*
9 *Medicaid Services and the Center for Medicare*
10 *Choices.*

11 (I) *GEOGRAPHIC DISTRIBUTION.*—*The steps*
12 *that should be taken to provide for an appro-*
13 *priate geographic distribution of administrative*
14 *law judges throughout the United States to en-*
15 *sure timely access to such judges.*

16 (J) *HIRING.*—*The steps that should be taken*
17 *to hire administrative law judges (and support*
18 *staff).*

19 (K) *PERFORMANCE STANDARDS.*—*The es-*
20 *tablishment of performance standards for admin-*
21 *istrative law judges with respect to timelines for*
22 *decisions in cases under title XVIII of the Social*
23 *Security Act.*

24 (L) *SHARED RESOURCES.*—*The feasibility*
25 *of the Secretary entering into such arrangements*

1 *with the Commissioner of Social Security as*
 2 *may be appropriate with respect to transferred*
 3 *functions under the plan to share office space,*
 4 *support staff, and other resources, with appro-*
 5 *priate reimbursement.*

6 (M) *TRAINING.*—*The training that should*
 7 *be provided to administrative law judges with*
 8 *respect to laws and regulations under title XVIII*
 9 *of the Social Security Act.*

10 (3) *ADDITIONAL INFORMATION.*—*The plan may*
 11 *also include recommendations for further congres-*
 12 *sional action, including modifications to the require-*
 13 *ments and deadlines established under section 1869 of*
 14 *the Social Security Act (as amended by sections 521*
 15 *and 522 of BIPA (114 Stat. 2763A–534) and this*
 16 *Act).*

17 (b) *GAO EVALUATION.*—*The Comptroller General of*
 18 *the United States shall—*

19 (1) *evaluate the plan submitted under subsection*
 20 (a); *and*

21 (2) *not later than 6 months after such submis-*
 22 *sion, submit to Congress, the Commissioner of Social*
 23 *Security, and the Secretary a report on such evalua-*
 24 *tion.*

1 (c) *SUBMISSION OF GAO REPORT REQUIRED BEFORE*
 2 *PLAN IMPLEMENTATION.*—*The Commissioner of Social Se-*
 3 *curity and the Secretary may not implement the plan devel-*
 4 *oped under subsection (a) before the date that is 6 months*
 5 *after the date the report required under subsection (b)(2)*
 6 *is submitted to the Commissioner and the Secretary.*

7 **SEC. 512. EXPEDITED ACCESS TO JUDICIAL REVIEW.**

8 (a) *IN GENERAL.*—*Section 1869(b) (42 U.S.C.*
 9 *1395ff(b)) is amended—*

10 (1) *in paragraph (1)(A), by inserting “, subject*
 11 *to paragraph (2),” before “to judicial review of the*
 12 *Secretary’s final decision”; and*

13 (2) *by adding at the end the following new para-*
 14 *graph:*

15 “(2) *EXPEDITED ACCESS TO JUDICIAL RE-*
 16 *VIEW.*—

17 “(A) *IN GENERAL.*—*The Secretary shall es-*
 18 *tablish a process under which a provider of serv-*
 19 *ices or supplier that furnishes an item or service*
 20 *or a beneficiary who has filed an appeal under*
 21 *paragraph (1) (other than an appeal filed under*
 22 *paragraph (1)(F)(i)) may obtain access to judi-*
 23 *cial review when a review entity (described in*
 24 *subparagraph (D)), on its own motion or at the*
 25 *request of the appellant, determines that the De-*

1 *partmental Appeals Board does not have the au-*
2 *thority to decide the question of law or regula-*
3 *tion relevant to the matters in controversy and*
4 *that there is no material issue of fact in dispute.*
5 *The appellant may make such request only once*
6 *with respect to a question of law or regulation*
7 *for a specific matter in dispute in a case of an*
8 *appeal.*

9 *“(B) PROMPT DETERMINATIONS.—If, after*
10 *or coincident with appropriately filing a request*
11 *for an administrative hearing, the appellant re-*
12 *quests a determination by the appropriate review*
13 *entity that the Departmental Appeals Board does*
14 *not have the authority to decide the question of*
15 *law or regulations relevant to the matters in con-*
16 *troversy and that there is no material issue of*
17 *fact in dispute, and if such request is accom-*
18 *panied by the documents and materials as the*
19 *appropriate review entity shall require for pur-*
20 *poses of making such determination, such review*
21 *entity shall make a determination on the request*
22 *in writing within 60 days after the date such re-*
23 *view entity receives the request and such accom-*
24 *panying documents and materials. Such a deter-*
25 *mination by such review entity shall be consid-*

1 *ered a final decision and not subject to review by*
 2 *the Secretary.*

3 “(C) *ACCESS TO JUDICIAL REVIEW.*—

4 “(i) *IN GENERAL.*—*If the appropriate*
 5 *review entity—*

6 “(I) *determines that there are no*
 7 *material issues of fact in dispute and*
 8 *that the only issues to be adjudicated*
 9 *are ones of law or regulation that the*
 10 *Departmental Appeals Board does not*
 11 *have authority to decide; or*

12 “(II) *fails to make such deter-*
 13 *mination within the period provided*
 14 *under subparagraph (B);*
 15 *then the appellant may bring a civil action*
 16 *as described in this subparagraph.*

17 “(ii) *DEADLINE FOR FILING.*—*Such*
 18 *action shall be filed, in the case described*
 19 *in—*

20 “(I) *clause (i)(I), within 60 days*
 21 *of the date of the determination de-*
 22 *scribed in such clause; or*

23 “(II) *clause (i)(II), within 60*
 24 *days of the end of the period provided*

1 under subparagraph (B) for the deter-
2 mination.

3 “(iii) *VENUE*.—Such action shall be
4 brought in the district court of the United
5 States for the judicial district in which the
6 appellant is located (or, in the case of an
7 action brought jointly by more than 1 ap-
8 plicant, the judicial district in which the
9 greatest number of applicants are located)
10 or in the District Court for the District of
11 Columbia.

12 “(iv) *INTEREST ON ANY AMOUNTS IN*
13 *CONTROVERSY*.—Where a provider of serv-
14 ices or supplier is granted judicial review
15 pursuant to this paragraph, the amount in
16 controversy (if any) shall be subject to an-
17 nual interest beginning on the first day of
18 the first month beginning after the 60-day
19 period as determined pursuant to clause (ii)
20 and equal to the rate of interest on obliga-
21 tions issued for purchase by the Federal
22 Supplementary Medical Insurance Trust
23 Fund for the month in which the civil ac-
24 tion authorized under this paragraph is
25 commenced, to be awarded by the reviewing

1 *court in favor of the prevailing party. No*
 2 *interest awarded pursuant to the preceding*
 3 *sentence shall be deemed income or cost for*
 4 *the purposes of determining reimbursement*
 5 *due providers of services, physicians, practi-*
 6 *tioners, and other suppliers under this Act.*

7 *(D) REVIEW ENTITY DEFINED.—For pur-*
 8 *poses of this subsection, the term ‘review entity’*
 9 *means an entity of up to 3 qualified reviewers*
 10 *drawn from existing appeals levels other than the*
 11 *redetermination level.*

12 *(b) APPLICATION TO PROVIDER AGREEMENT DETER-*
 13 *MINATIONS.—Section 1866(h)(1) (42 U.S.C. 1395cc(h)(1))*
 14 *is amended—*

15 *(1) by inserting “(A)” after “(h)(1)”;* and
 16 *(2) by adding at the end the following new sub-*
 17 *paragraph:*

18 *“(B) An institution or agency described in subpara-*
 19 *graph (A) that has filed for a hearing under subparagraph*
 20 *(A) shall have expedited access to judicial review under this*
 21 *subparagraph in the same manner as providers of services,*
 22 *suppliers, and beneficiaries may obtain expedited access to*
 23 *judicial review under the process established under section*
 24 *1869(b)(2). Nothing in this subparagraph shall be construed*
 25 *to affect the application of any remedy imposed under sec-*

1 *tion 1819 during the pendency of an appeal under this sub-*
 2 *paragraph.”.*

3 *(c) GAO STUDY AND REPORT ON ACCESS TO JUDICIAL*
 4 *REVIEW.—*

5 *(1) STUDY.—The Comptroller General of the*
 6 *United States shall conduct a study on the access of*
 7 *medicare beneficiaries and health care providers to*
 8 *judicial review of actions of the Secretary and the De-*
 9 *partment of Health and Human Services with respect*
 10 *to items and services under title XVIII of the Social*
 11 *Security Act subsequent to February 29, 2000, the*
 12 *date of the decision of Shalala, Secretary of Health*
 13 *and Human Services, et al. v. Illinois Council on*
 14 *Long Term Care, Inc. (529 U.S. 1 (2000)).*

15 *(2) REPORT.—Not later than 1 year after the*
 16 *date of enactment of this Act, the Comptroller General*
 17 *shall submit to Congress a report on the study con-*
 18 *ducted under paragraph (1) together with such rec-*
 19 *ommendations as the Comptroller General determines*
 20 *to be appropriate.*

21 *(d) CONFORMING AMENDMENT.—Section*
 22 *1869(b)(1)(F)(ii) (42 U.S.C. 1395ff(b)(1)(F)(ii)) is amend-*
 23 *ed to read as follows:*

24 *“(ii) REFERENCE TO EXPEDITED AC-*
 25 *CESS TO JUDICIAL REVIEW.—For the provi-*

1 *sion relating to expedited access to judicial*
 2 *review, see paragraph (2).”.*

3 *(e) EFFECTIVE DATE.—The amendments made by this*
 4 *section shall apply to appeals filed on or after October 1,*
 5 *2004.*

6 **SEC. 513. EXPEDITED REVIEW OF CERTAIN PROVIDER**
 7 **AGREEMENT DETERMINATIONS.**

8 *(a) TERMINATION AND CERTAIN OTHER IMMEDIATE*
 9 *REMEDIES.—*

10 *(1) IN GENERAL.—The Secretary shall develop*
 11 *and implement a process to expedite proceedings*
 12 *under sections 1866(h) of the Social Security Act (42*
 13 *U.S.C. 1395cc(h)) in which—*

14 *(A) the remedy of termination of participa-*
 15 *tion has been imposed;*

16 *(B) a sanction described in clause (i) or*
 17 *(iii) of section 1819(h)(2)(B) of such Act (42*
 18 *U.S.C. 1395i–3(h)(2)(B)) has been imposed, but*
 19 *only if such sanction has been imposed on an*
 20 *immediate basis; or*

21 *(C) the Secretary has required a skilled*
 22 *nursing facility to suspend operations of a nurse*
 23 *aide training program.*

24 *(2) PRIORITY FOR CASES OF TERMINATION.—*
 25 *Under the process described in paragraph (1), pri-*

1 ority shall be provided in cases of termination de-
 2 scribed in subparagraph (A) of such paragraph.

3 (b) *INCREASED FINANCIAL SUPPORT.*—In addition to
 4 any amounts otherwise appropriated, to reduce by 50 per-
 5 cent the average time for administrative determinations on
 6 appeals under section 1866(h) of the Social Security Act
 7 (42 U.S.C. 1395cc(h)), there are authorized to be appro-
 8 priated (in appropriate part from the Federal Hospital In-
 9 surance Trust Fund and the Federal Supplementary Med-
 10 ical Insurance Trust Fund) to the Secretary such sums for
 11 fiscal year 2004 and each subsequent fiscal year as may
 12 be necessary to increase the number of administrative law
 13 judges (and their staffs) at the Departmental Appeals Board
 14 of the Department of Health and Human Services and to
 15 educate such judges and staff on long-term care issues.

16 **SEC. 514. REVISIONS TO MEDICARE APPEALS PROCESS.**

17 (a) *TIMEFRAMES FOR THE COMPLETION OF THE*
 18 *RECORD.*—Section 1869(b) (42 U.S.C. 1395ff(b)), as
 19 amended by section 512(a)(2), is amended by adding at the
 20 end the following new paragraph:

21 “(3) *TIMELY COMPLETION OF THE RECORD.*—

22 “(A) *DEADLINE.*—Subject to subparagraph
 23 (B), the deadline to complete the record in a
 24 hearing before an administrative law judge or a
 25 review by the Departmental Appeals Board is 90

1 *days after the date the request for the review or*
2 *hearing is filed.*

3 “(B) *EXTENSIONS FOR GOOD CAUSE.—The*
4 *person filing a request under subparagraph (A)*
5 *may request an extension of such deadline for*
6 *good cause. The administrative law judge, in the*
7 *case of a hearing, and the Departmental Appeals*
8 *Board, in the case of a review, may extend such*
9 *deadline based upon a finding of good cause to*
10 *a date specified by the judge or Board, as the*
11 *case may be.*

12 “(C) *DELAY IN DECISION DEADLINES UNTIL*
13 *COMPLETION OF RECORD.—Notwithstanding any*
14 *other provision of this section, the deadlines oth-*
15 *erwise established under subsection (d) for the*
16 *making of determinations in hearings or review*
17 *under this section are 90 days after the date on*
18 *which the record is complete.*

19 “(D) *COMPLETE RECORD DESCRIBED.—For*
20 *purposes of this paragraph, a record is complete*
21 *when the administrative law judge, in the case*
22 *of a hearing, or the Departmental Appeals*
23 *Board, in the case of a review, has received—*

1 “(i) written or testimonial evidence, or
 2 both, submitted by the person filing the re-
 3 quest,

4 “(ii) written or oral argument, or both,
 5 “(iii) the decision of, and the record
 6 for, the prior level of appeal, and

7 “(iv) such other evidence as such judge
 8 or Board, as the case may be, determines is
 9 required to make a determination on the re-
 10 quest.”.

11 (b) *USE OF PATIENTS’ MEDICAL RECORDS.*—Section
 12 1869(c)(3)(B)(i) (42 U.S.C. 1395ff(c)(3)(B)(i)) is amended
 13 by inserting “(including the medical records of the indi-
 14 vidual involved)” after “clinical experience”.

15 (c) *NOTICE REQUIREMENTS FOR MEDICARE AP-*
 16 *PEALS.*—

17 (1) *INITIAL DETERMINATIONS AND REDETER-*
 18 *MINATIONS.*—Section 1869(a) (42 U.S.C. 1395ff(a)) is
 19 amended by adding at the end the following new
 20 paragraph:

21 “(4) *REQUIREMENTS OF NOTICE OF DETERMINA-*
 22 *TIONS AND REDETERMINATIONS.*—A written notice of
 23 a determination on an initial determination or on a
 24 redetermination, insofar as such determination or re-
 25 determination results in a denial of a claim for bene-

fits, shall be provided in printed form and written in
a manner to be understood by the beneficiary and
shall include—

“(A) the reasons for the determination, including, as appropriate—

“(i) upon request in the case of an initial determination, the provision of the policy, manual, or regulation that resulted in the denial; and

“(ii) in the case of a redetermination, a summary of the clinical or scientific evidence used in making the determination (as appropriate);

“(B) the procedures for obtaining additional information concerning the determination or redetermination; and

“(C) notification of the right to seek a redetermination or otherwise appeal the determination and instructions on how to initiate such a redetermination or appeal under this section.”.

(2) *RECONSIDERATIONS.*—Section 1869(c)(3)(E) (42 U.S.C. 1395ff(c)(3)(E)) is amended to read as follows:

“(E) *EXPLANATION OF DECISION.*—Any decision with respect to a reconsideration of a

1 *qualified independent contractor shall be in*
 2 *writing in a manner to be understood by the*
 3 *beneficiary and shall include—*

4 *“(i) to the extent appropriate, a de-*
 5 *tailed explanation of the decision as well as*
 6 *a discussion of the pertinent facts and ap-*
 7 *plicable regulations applied in making such*
 8 *decision;*

9 *“(ii) a notification of the right to ap-*
 10 *peal such determination and instructions on*
 11 *how to initiate such appeal under this sec-*
 12 *tion; and*

13 *“(iii) in the case of a determination of*
 14 *whether an item or service is reasonable and*
 15 *necessary for the diagnosis or treatment of*
 16 *illness or injury (under section*
 17 *1862(a)(1)(A)) an explanation of the med-*
 18 *ical or scientific rationale for the decision.”.*

19 (3) *APPEALS.—Section 1869(d) (42 U.S.C.*
 20 *1395ff(d)) is amended—*

21 *(A) in the heading, by inserting “; NOTICE”*
 22 *after “SECRETARY”; and*

23 *(B) by adding at the end the following new*
 24 *paragraph:*

1 “(4) NOTICE.—Notice of the decision of an ad-
 2 ministrative law judge shall be in writing in a man-
 3 ner to be understood by the beneficiary and shall
 4 include—

5 “(A) the specific reasons for the determina-
 6 tion (including, to the extent appropriate, a
 7 summary of the clinical or scientific evidence
 8 used in making the determination);

9 “(B) the procedures for obtaining addi-
 10 tional information concerning the decision; and

11 “(C) notification of the right to appeal the
 12 decision and instructions on how to initiate such
 13 an appeal under this section.”.

14 (4) PREPARATION OF RECORD FOR APPEAL.—
 15 Section 1869(c)(3)(J) (42 U.S.C. 1395ff(c)(3)(J)) is
 16 amended by striking “such information as is required
 17 for an appeal” and inserting “the record for the ap-
 18 peal”.

19 (d) QUALIFIED INDEPENDENT CONTRACTORS.—

20 (1) ELIGIBILITY REQUIREMENTS OF QUALIFIED
 21 INDEPENDENT CONTRACTORS.—Section 1869(c) (42
 22 U.S.C. 1395ff(c)) is amended—

23 (A) in paragraph (2)—

24 (i) by inserting “(except in the case of
 25 a utilization and quality control peer re-

1 *view organization, as defined in section*
2 *1152)” after “means an entity or organiza-*
3 *tion that”; and*

4 *(ii) by striking the period at the end*
5 *and inserting the following: “and meets the*
6 *following requirements:*

7 *“(A) GENERAL REQUIREMENTS.—*

8 *“(i) The entity or organization has*
9 *(directly or through contracts or other ar-*
10 *rangements) sufficient medical, legal, and*
11 *other expertise (including knowledge of the*
12 *program under this title) and sufficient*
13 *staffing to carry out duties of a qualified*
14 *independent contractor under this section*
15 *on a timely basis.*

16 *“(ii) The entity or organization has*
17 *provided assurances that it will conduct ac-*
18 *tivities consistent with the applicable re-*
19 *quirements of this section, including that it*
20 *will not conduct any activities in a case*
21 *unless the independence requirements of*
22 *subparagraph (B) are met with respect to*
23 *the case.*

1 “(iii) *The entity or organization meets*
 2 *such other requirements as the Secretary*
 3 *provides by regulation.*

4 “(B) *INDEPENDENCE REQUIREMENTS.—*

5 “(i) *IN GENERAL.—Subject to clause*
 6 *(ii), an entity or organization meets the*
 7 *independence requirements of this subpara-*
 8 *graph with respect to any case if the*
 9 *entity—*

10 “(I) *is not a related party (as de-*
 11 *finied in subsection (g)(5));*

12 “(II) *does not have a material fa-*
 13 *miliar, financial, or professional rela-*
 14 *tionship with such a party in relation*
 15 *to such case; and*

16 “(III) *does not otherwise have a*
 17 *conflict of interest with such a party*
 18 *(as determined under regulations).*

19 “(ii) *EXCEPTION FOR COMPENSA-*
 20 *TION.—Nothing in clause (i) shall be con-*
 21 *strued to prohibit receipt by a qualified*
 22 *independent contractor of compensation*
 23 *from the Secretary for the conduct of activi-*
 24 *ties under this section if the compensation*
 25 *is provided consistent with clause (iii).*

1 “(iii) *LIMITATIONS ON ENTITY COM-*
 2 *PENSATION.*—*Compensation provided by the*
 3 *Secretary to a qualified independent con-*
 4 *tractor in connection with reviews under*
 5 *this section shall not be contingent on any*
 6 *decision rendered by the contractor or by*
 7 *any reviewing professional.”; and*

8 *(B) in paragraph (3)(A), by striking “, and*
 9 *shall have sufficient training and expertise in*
 10 *medical science and legal matters to make recon-*
 11 *siderations under this subsection”.*

12 (2) *ELIGIBILITY REQUIREMENTS FOR REVIEW-*
 13 *ERS.*—*Section 1869 (42 U.S.C. 1395ff) is amended—*

14 *(A) by amending subsection (c)(3)(D) to*
 15 *read as follows:*

16 “(D) *QUALIFICATIONS OF REVIEWERS.*—*The*
 17 *requirements of subsection (g) shall be met (relat-*
 18 *ing to qualifications of reviewing profes-*
 19 *sionals).”; and*

20 *(B) by adding at the end the following new*
 21 *subsection:*

22 “(g) *QUALIFICATIONS OF REVIEWERS.*—

23 “(1) *IN GENERAL.*—*In reviewing determinations*
 24 *under this section, a qualified independent contractor*
 25 *shall assure that—*

1 “(A) each individual conducting a review
2 shall meet the qualifications of paragraph (2);

3 “(B) compensation provided by the con-
4 tractor to each such reviewer is consistent with
5 paragraph (3); and

6 “(C) in the case of a review by a panel de-
7 scribed in subsection (c)(3)(B) composed of phy-
8 sicians or other health care professionals (each in
9 this subsection referred to as a ‘reviewing profes-
10 sional’), each reviewing professional meets the
11 qualifications described in paragraph (4).

12 “(2) INDEPENDENCE.—

13 “(A) IN GENERAL.—Subject to subpara-
14 graph (B), each individual conducting a review
15 in a case shall—

16 “(i) not be a related party (as defined
17 in paragraph (5));

18 “(ii) not have a material familial, fi-
19 nancial, or professional relationship with
20 such a party in the case under review; and

21 “(iii) not otherwise have a conflict of
22 interest with such a party (as determined
23 under regulations).

24 “(B) EXCEPTION.—Nothing in subpara-
25 graph (A) shall be construed to—

1 “(i) prohibit an individual, solely on
2 the basis of affiliation with a fiscal inter-
3 mediary, carrier, or other contractor, from
4 serving as a reviewing professional if—

5 “(I) a nonaffiliated individual is
6 not reasonably available;

7 “(II) the affiliated individual is
8 not involved in the provision of items
9 or services in the case under review;

10 “(III) the fact of such an affili-
11 ation is disclosed to the Secretary and
12 the beneficiary (or authorized rep-
13 resentative) and neither party objects;
14 and

15 “(IV) the affiliated individual is
16 not an employee of the intermediary,
17 carrier, or contractor and does not pro-
18 vide services exclusively or primarily
19 to or on behalf of such intermediary,
20 carrier, or contractor;

21 “(ii) prohibit an individual who has
22 staff privileges at the institution where the
23 treatment involved takes place from serving
24 as a reviewer merely on the basis of such af-
25 filiation if the affiliation is disclosed to the

1 *Secretary and the beneficiary (or authorized*
 2 *representative), and neither party objects; or*
 3 *“(iii) prohibit receipt of compensation*
 4 *by a reviewing professional from a con-*
 5 *tractor if the compensation is provided con-*
 6 *sistent with paragraph (3).*

7 *“(3) LIMITATIONS ON REVIEWER COMPENSA-*
 8 *TION.—Compensation provided by a qualified inde-*
 9 *pendent contractor to a reviewer in connection with*
 10 *a review under this section shall not be contingent on*
 11 *the decision rendered by the reviewer.*

12 *“(4) LICENSURE AND EXPERTISE.—Each review-*
 13 *ing professional shall be a physician (allopathic or*
 14 *osteopathic) or health care professional who—*

15 *“(A) is appropriately credentialed or li-*
 16 *censed in 1 or more States to deliver health care*
 17 *services; and*

18 *“(B) has medical expertise in the field of*
 19 *practice that is appropriate for the items or serv-*
 20 *ices at issue.*

21 *“(5) RELATED PARTY DEFINED.—For purposes*
 22 *of this section, the term ‘related party’ means, with*
 23 *respect to a case under this title involving an indi-*
 24 *vidual beneficiary, any of the following:*

1 “(A) *The Secretary, the medicare adminis-*
 2 *trative contractor involved, or any fiduciary, of-*
 3 *ficer, director, or employee of the Department of*
 4 *Health and Human Services, or of such con-*
 5 *tractor.*

6 “(B) *The individual (or authorized rep-*
 7 *resentative).*

8 “(C) *The health care professional that pro-*
 9 *vides the items or services involved in the case.*

10 “(D) *The institution at which the items or*
 11 *services (or treatment) involved in the case are*
 12 *provided.*

13 “(E) *The manufacturer of any drug or*
 14 *other item that is included in the items or serv-*
 15 *ices involved in the case.*

16 “(F) *Any other party determined under any*
 17 *regulations to have a substantial interest in the*
 18 *case involved.”.*

19 (3) *NUMBER OF QUALIFIED INDEPENDENT CON-*
 20 *TRACTORS.—Section 1869(c)(4) (42 U.S.C.*
 21 *1395ff(c)(4)) is amended by striking “12” and insert-*
 22 *ing “4”.*

23 (e) *IMPLEMENTATION OF CERTAIN BIPA REFORMS.—*

1 (1) *DELAY IN CERTAIN BIPA REFORMS.*—Section
 2 521(d) of BIPA (114 Stat. 2763A–543) is amended to
 3 read as follows:

4 “(d) *EFFECTIVE DATE.*—

5 “(1) *IN GENERAL.*—Except as specified in para-
 6 graph (2), the amendments made by this section shall
 7 apply with respect to initial determinations made on
 8 or after December 1, 2004.

9 “(2) *EXPEDITED PROCEEDINGS AND RECONSID-*
 10 *ERATION REQUIREMENTS.*—For the following provi-
 11 sions, the amendments made by subsection (a) shall
 12 apply with respect to initial determinations made on
 13 or after October 1, 2003:

14 “(A) Subsection (b)(1)(F)(i) of section 1869
 15 of the Social Security Act.

16 “(B) Subsection (c)(3)(C)(iii) of such sec-
 17 tion.

18 “(C) Subsection (c)(3)(C)(iv) of such section
 19 to the extent that it applies to expedited recon-
 20 siderations under subsection (c)(3)(C)(iii) of
 21 such section.

22 “(3) *TRANSITIONAL USE OF PEER REVIEW ORGA-*
 23 *NIZATIONS TO CONDUCT EXPEDITED RECONSIDER-*
 24 *ATIONS UNTIL QICS ARE OPERATIONAL.*—Expedited
 25 reconsiderations of initial determinations under sec-

1 *tion 1869(c)(3)(C)(iii) of the Social Security Act*
 2 *shall be made by peer review organizations until*
 3 *qualified independent contractors are available for*
 4 *such expedited reconsiderations.”.*

5 (2) *CONFORMING AMENDMENTS.—Section 521(c)*
 6 *of BIPA (114 Stat. 2763A–543) and section*
 7 *1869(c)(3)(C)(iii)(III) of the Social Security Act (42*
 8 *U.S.C. 1395ff(c)(3)(C)(iii)(III)), as added by section*
 9 *521 of BIPA, are repealed.*

10 (f) *EFFECTIVE DATE.—The amendments made by this*
 11 *section shall be effective as if included in the enactment of*
 12 *the respective provisions of subtitle C of title V of BIPA,*
 13 *114 Stat. 2763A–534.*

14 (g) *TRANSITION.—In applying section 1869(g) of the*
 15 *Social Security Act (as added by subsection (d)(2)), any*
 16 *reference to a medicare administrative contractor shall be*
 17 *deemed to include a reference to a fiscal intermediary under*
 18 *section 1816 of the Social Security Act (42 U.S.C. 1395h)*
 19 *and a carrier under section 1842 of such Act (42 U.S.C.*
 20 *1395u).*

1 **SEC. 515. HEARING RIGHTS RELATED TO DECISIONS BY**
 2 **THE SECRETARY TO DENY OR NOT RENEW A**
 3 **MEDICARE ENROLLMENT AGREEMENT; CON-**
 4 **SULTATION BEFORE CHANGING PROVIDER**
 5 **ENROLLMENT FORMS.**

6 *(a) HEARING RIGHTS.—*

7 *(1) IN GENERAL.—Section 1866 (42 U.S.C.*
 8 *1395cc) is amended by adding at the end the fol-*
 9 *lowing new subsection:*

10 *“(j) HEARING RIGHTS IN CASES OF DENIAL OR NON-*
 11 *RENEWAL.—The Secretary shall establish by regulation pro-*
 12 *cedures under which—*

13 *“(1) there are deadlines for actions on applica-*
 14 *tions for enrollment (and, if applicable, renewal of*
 15 *enrollment); and*

16 *“(2) providers of services, physicians, practi-*
 17 *tioners, and suppliers whose application to enroll (or,*
 18 *if applicable, to renew enrollment) are denied are*
 19 *provided a mechanism to appeal such denial and a*
 20 *deadline for consideration of such appeals.”.*

21 *(2) EFFECTIVE DATE.—The Secretary shall pro-*
 22 *vide for the establishment of the procedures under the*
 23 *amendment made by paragraph (1) within 18 months*
 24 *after the date of enactment of this Act.*

25 *(b) CONSULTATION BEFORE CHANGING PROVIDER EN-*
 26 *ROLLMENT FORMS.—Section 1871 (42 U.S.C. 1395hh), as*

1 amended by sections 502 and 503, is amended by adding
 2 at the end the following new subsection:

3 “(f) The Secretary shall consult with providers of serv-
 4 ices, physicians, practitioners, and suppliers before making
 5 changes in the provider enrollment forms required of such
 6 providers, physicians, practitioners, and suppliers to be eli-
 7 gible to submit claims for which payment may be made
 8 under this title.”.

9 **SEC. 516. APPEALS BY PROVIDERS WHEN THERE IS NO**
 10 **OTHER PARTY AVAILABLE.**

11 (a) *IN GENERAL.*—Section 1870 (42 U.S.C. 1395gg)
 12 is amended by adding at the end the following new sub-
 13 section:

14 “(h) Notwithstanding subsection (f) or any other pro-
 15 vision of law, the Secretary shall permit a provider of serv-
 16 ices, physician, practitioner, or other supplier to appeal
 17 any determination of the Secretary under this title relating
 18 to services rendered under this title to an individual who
 19 subsequently dies if there is no other party available to ap-
 20 peal such determination.”.

21 (b) *EFFECTIVE DATE.*—The amendment made by sub-
 22 section (a) shall take effect on the date of enactment of this
 23 Act and shall apply to items and services furnished on or
 24 after such date.

1 **SEC. 517. PROVIDER ACCESS TO REVIEW OF LOCAL COV-**
 2 **ERAGE DETERMINATIONS.**

3 (a) *PROVIDER ACCESS TO REVIEW OF LOCAL COV-*
 4 *ERAGE DETERMINATIONS.*—Section 1869(f)(5) (42 U.S.C.
 5 1395ff(f)(5)) is amended to read as follows:

6 “(5) *AGGRIEVED PARTY DEFINED.*—In this sec-
 7 tion, the term ‘aggrieved party’ means—

8 “(A) with respect to a national coverage de-
 9 termination, an individual entitled to benefits
 10 under part A, or enrolled under part B, or both,
 11 who is in need of the items or services that are
 12 the subject of the coverage determination; and

13 “(B) with respect to a local coverage
 14 determination—

15 “(i) an individual who is entitled to
 16 benefits under part A, or enrolled under
 17 part B, or both, who is adversely affected by
 18 such a determination; or

19 “(ii) a provider of services, physician,
 20 practitioner, or supplier that is adversely
 21 affected by such a determination.”.

22 (b) *CLARIFICATION OF LOCAL COVERAGE DETERMINA-*
 23 *TION DEFINITION.*—Section 1869(f)(2)(B) (42 U.S.C.
 24 1395ff(f)(2)(B)) is amended by inserting “, including,
 25 where appropriate, the specific requirements and clinical

1 *indications relating to the medical necessity of an item or*
 2 *service” before the period at the end.*

3 *(c) REQUEST FOR LOCAL COVERAGE DETERMINATIONS*
 4 *BY PROVIDERS.—Section 1869 (42 U.S.C. 1395ff), as*
 5 *amended by section 514(d)(2)(B), is amended by adding at*
 6 *the end the following new subsection:*

7 *“(h) REQUEST FOR LOCAL COVERAGE DETERMINA-*
 8 *TIONS BY PROVIDERS.—*

9 *“(1) ESTABLISHMENT OF PROCESS.—The Sec-*
 10 *retary shall establish a process under which a pro-*
 11 *vider of services, physician, practitioner, or supplier*
 12 *who certifies that they meet the requirements estab-*
 13 *lished in paragraph (3) may request a local coverage*
 14 *determination in accordance with the succeeding pro-*
 15 *visions of this subsection.*

16 *“(2) PROVIDER LOCAL COVERAGE DETERMINA-*
 17 *TION REQUEST DEFINED.—In this subsection, the*
 18 *term ‘provider local coverage determination request’*
 19 *means a request, filed with the Secretary, at such*
 20 *time and in such form and manner as the Secretary*
 21 *may specify, that the Secretary, pursuant to para-*
 22 *graph (4)(A), require a fiscal intermediary, carrier,*
 23 *or program safeguard contractor to make or revise a*
 24 *local coverage determination under this section with*
 25 *respect to an item or service.*

1 “(3) *REQUEST REQUIREMENTS.*—Under the
2 *process established under paragraph (1), by not later*
3 *than 30 days after the date on which a provider local*
4 *coverage determination request is filed under para-*
5 *graph (1), the Secretary shall determine whether such*
6 *request establishes that—*

7 “(A) *there have been at least 5 reversals of*
8 *redeterminations made by a fiscal intermediary*
9 *or carrier after a hearing before an administra-*
10 *tive law judge on claims submitted by the pro-*
11 *vider in at least 2 different cases before an ad-*
12 *ministrative law judge;*

13 “(B) *each reversal described in subpara-*
14 *graph (A) involves substantially similar mate-*
15 *rial facts;*

16 “(C) *each reversal described in subpara-*
17 *graph (A) involves the same medical necessity*
18 *issue; and*

19 “(D) *at least 50 percent of the total number*
20 *of claims submitted by such provider within the*
21 *past year involving the substantially similar*
22 *material facts described in subparagraph (B)*
23 *and the same medical necessity issue described in*
24 *subparagraph (C) have been denied and have*
25 *been reversed by an administrative law judge.*

1 “(4) *APPROVAL OR REJECTION OF REQUEST.*—

2 “(A) *APPROVAL OF REQUEST.*—If the Sec-
3 retary determines that subparagraphs (A)
4 through (D) of paragraph (3) have been satisfied,
5 the Secretary shall require the fiscal inter-
6 mediary, carrier, or program safeguard con-
7 tractor identified in the provider local coverage
8 determination request, to make or revise a local
9 coverage determination with respect to the item
10 or service that is the subject of the request not
11 later than the date that is 210 days after the
12 date on which the Secretary makes the deter-
13 mination. Such fiscal intermediary, carrier, or
14 program safeguard contractor shall retain the
15 discretion to determine whether or not, and/or
16 the circumstances under which, to cover the item
17 or service for which a local coverage determina-
18 tion is requested. Nothing in this subsection shall
19 be construed to require a fiscal intermediary,
20 carrier or program safeguard contractor to de-
21 velop a local coverage determination that is in-
22 consistent with any national coverage determina-
23 tion, or any coverage provision in this title or in
24 regulation, manual, or interpretive guidance of
25 the Secretary.

1 “(B) *REJECTION OF REQUEST.*—If the Sec-
 2 retary determines that subparagraphs (A)
 3 through (D) of paragraph (3) have not been sat-
 4 isfied, the Secretary shall reject the provider
 5 local coverage determination request and shall
 6 notify the provider of services, physician, practi-
 7 tioner, or supplier that filed the request of the
 8 reason for such rejection and no further pro-
 9 ceedings in relation to such request shall be con-
 10 ducted.”.

11 (d) *STUDY AND REPORT ON THE USE OF CONTRAC-*
 12 *TORS TO MONITOR MEDICARE APPEALS.*—

13 (1) *STUDY.*—The Secretary shall conduct a study
 14 on the feasibility and advisability of requiring fiscal
 15 intermediaries and carriers to monitor and track—

16 (A) the subject matter and status of claims
 17 denied by the fiscal intermediary or carrier (as
 18 applicable) that are appealed under section 1869
 19 of the Social Security Act (42 U.S.C. 1395ff), as
 20 added by section 522 of BIPA (114 Stat. 2763A–
 21 543) and amended by this Act; and

22 (B) any final determination made with re-
 23 spect to such claims.

24 (2) *REPORT.*—Not later than the date that is 1
 25 year after the date of enactment of this Act, the Sec-

1 retary shall submit to Congress a report on the study
 2 conducted under paragraph (1) together with such
 3 recommendations for legislation and administrative
 4 action as the Commission determines appropriate.

5 (e) *AUTHORIZATION OF APPROPRIATIONS.*—There are
 6 authorized to be appropriated such sums as are necessary
 7 to carry out the amendments made by subsections (a), (b),
 8 and (c).

9 (f) *EFFECTIVE DATES.*—

10 (1) *PROVIDER ACCESS TO REVIEW OF LOCAL*
 11 *COVERAGE DETERMINATIONS.*—The amendments
 12 made by subsections (a) and (b) shall apply to—

13 (A) any review of any local coverage deter-
 14 mination filed on or after October 1, 2003;

15 (B) any request to make such a determina-
 16 tion made on or after such date; or

17 (C) any local coverage determination made
 18 on or after such date.

19 (2) *PROVIDER LOCAL COVERAGE DETERMINATION*
 20 *REQUESTS.*—The amendment made by subsection (c)
 21 shall apply with respect to provider local coverage de-
 22 termination requests (as defined in section 1869(h)(2)
 23 of the Social Security Act, as added by subsection (c))
 24 filed on or after the date of enactment of this Act.

1 **SEC. 518. REVISIONS TO APPEALS TIMEFRAMES.**

2 *Section 1869 (42 U.S.C. 1395ff) is amended—*

3 *(1) in subsection (a)(3)(C)(ii), by striking “30-*
 4 *day period” each place it appears and inserting “60-*
 5 *day period”;*

6 *(2) in subsection (c)(3)(C)(i), by striking “30-*
 7 *day period” and inserting “60-day period”;*

8 *(3) in subsection (d)(1)(A), by striking “90-day*
 9 *period” and inserting “120-day period”; and*

10 *(4) in subsection (d)(2)(A), by striking “90-day*
 11 *period” and inserting “120-day period”.*

12 **SEC. 519. ELIMINATION OF REQUIREMENT TO USE SOCIAL**
 13 **SECURITY ADMINISTRATION ADMINISTRA-**
 14 **TIVE LAW JUDGES.**

15 *The first sentence of section 1869(f)(2)(A)(i) (42*
 16 *U.S.C. 1395ff(f)(2)(A)(i)) is amended by striking “of the*
 17 *Social Security Administration”.*

18 **SEC. 520. ELIMINATION OF REQUIREMENT FOR DE NOVO**
 19 **REVIEW BY THE DEPARTMENTAL APPEALS**
 20 **BOARD.**

21 *Section 1869(d)(2) (42 U.S.C. 1395ff(d)(2)) is amend-*
 22 *ed to read as follows:*

23 *“(2) DEPARTMENTAL APPEALS BOARD RE-*
 24 *VIEW.—The Departmental Appeals Board of the De-*
 25 *partment of Health and Human Services shall con-*
 26 *duct and conclude a review of the decision on a hear-*

1 *ing described in paragraph (1) and make a decision*
 2 *or remand the case to the administrative law judge*
 3 *for reconsideration by not later than the end of the*
 4 *90-day period beginning on the date a request for re-*
 5 *view has been timely filed.”.*

6 ***Subtitle C—Contracting Reform***

7 ***SEC. 521. INCREASED FLEXIBILITY IN MEDICARE ADMINIS-*** 8 ***TRATION.***

9 *(a) CONSOLIDATION AND FLEXIBILITY IN MEDICARE*
 10 *ADMINISTRATION.—*

11 *(1) IN GENERAL.—Title XVIII is amended by in-*
 12 *serting after section 1874 the following new section:*

13 *“CONTRACTS WITH MEDICARE ADMINISTRATIVE*
 14 *CONTRACTORS*

15 *“SEC. 1874A. (a) AUTHORITY.—*

16 *“(1) AUTHORITY TO ENTER INTO CONTRACTS.—*
 17 *The Secretary may enter into contracts with any eli-*
 18 *gible entity to serve as a medicare administrative*
 19 *contractor with respect to the performance of any or*
 20 *all of the functions described in paragraph (4) or*
 21 *parts of those functions (or, to the extent provided in*
 22 *a contract, to secure performance thereof by other en-*
 23 *tities).*

24 *“(2) ELIGIBILITY OF ENTITIES.—An entity is el-*
 25 *igible to enter into a contract with respect to the per-*

1 *formance of a particular function described in para-*
 2 *graph (4) only if—*

3 *“(A) the entity has demonstrated capability*
 4 *to carry out such function;*

5 *“(B) the entity complies with such conflict*
 6 *of interest standards as are generally applicable*
 7 *to Federal acquisition and procurement;*

8 *“(C) the entity has sufficient assets to fi-*
 9 *nancially support the performance of such func-*
 10 *tion; and*

11 *“(D) the entity meets such other require-*
 12 *ments as the Secretary may impose.*

13 *“(3) MEDICARE ADMINISTRATIVE CONTRACTOR*
 14 *DEFINED.—For purposes of this title and title XI—*

15 *“(A) IN GENERAL.—The term ‘medicare ad-*
 16 *ministrative contractor’ means an agency, orga-*
 17 *nization, or other person with a contract under*
 18 *this section.*

19 *“(B) APPROPRIATE MEDICARE ADMINISTRA-*
 20 *TIVE CONTRACTOR.—With respect to the perform-*
 21 *ance of a particular function in relation to an*
 22 *individual entitled to benefits under part A or*
 23 *enrolled under part B, or both, a specific pro-*
 24 *vider of services, physician, practitioner, facility,*
 25 *or supplier (or class of such providers of services,*

1 *physicians, practitioners, facilities, or suppliers),*
 2 *the ‘appropriate’ medicare administrative con-*
 3 *tractor is the medicare administrative contractor*
 4 *that has a contract under this section with re-*
 5 *spect to the performance of that function in rela-*
 6 *tion to that individual, provider of services, phy-*
 7 *sician, practitioner, facility, or supplier or class*
 8 *of provider of services, physician, practitioner,*
 9 *facility, or supplier.*

10 “(4) *FUNCTIONS DESCRIBED.*—*The functions re-*
 11 *ferred to in paragraphs (1) and (2) are payment*
 12 *functions (including the function of developing local*
 13 *coverage determinations, as defined in section*
 14 *1869(f)(2)(B)), provider services functions, and bene-*
 15 *ficiary services functions as follows:*

16 “(A) *DETERMINATION OF PAYMENT*
 17 *AMOUNTS.*—*Determining (subject to the provi-*
 18 *sions of section 1878 and to such review by the*
 19 *Secretary as may be provided for by the con-*
 20 *tracts) the amount of the payments required pur-*
 21 *suant to this title to be made to providers of*
 22 *services, physicians, practitioners, facilities, sup-*
 23 *pliers, and individuals.*

24 “(B) *MAKING PAYMENTS.*—*Making pay-*
 25 *ments described in subparagraph (A) (including*

1 *receipt, disbursement, and accounting for funds*
2 *in making such payments).*

3 “(C) *BENEFICIARY EDUCATION AND ASSIST-*
4 *ANCE.—Serving as a center for, and commu-*
5 *nicating to individuals entitled to benefits under*
6 *part A or enrolled under part B, or both, with*
7 *respect to education and outreach for those indi-*
8 *viduals, and assistance with specific issues, con-*
9 *cerns, or problems of those individuals.*

10 “(D) *PROVIDER CONSULTATIVE SERV-*
11 *ICES.—Providing consultative services to institu-*
12 *tions, agencies, and other persons to enable them*
13 *to establish and maintain fiscal records nec-*
14 *essary for purposes of this title and otherwise to*
15 *qualify as providers of services, physicians, prac-*
16 *titioners, facilities, or suppliers.*

17 “(E) *COMMUNICATION WITH PROVIDERS.—*
18 *Serving as a center for, and communicating to*
19 *providers of services, physicians, practitioners,*
20 *facilities, and suppliers, any information or in-*
21 *structions furnished to the medicare administra-*
22 *tive contractor by the Secretary, and serving as*
23 *a channel of communication from such pro-*
24 *viders, physicians, practitioners, facilities, and*
25 *suppliers to the Secretary.*

1 “(F) *PROVIDER EDUCATION AND TECHNICAL*
 2 *ASSISTANCE.—Performing the functions de-*
 3 *scribed in subsections (e) and (f), relating to*
 4 *education, training, and technical assistance to*
 5 *providers of services, physicians, practitioners,*
 6 *facilities, and suppliers.*

7 “(G) *ADDITIONAL FUNCTIONS.—Performing*
 8 *such other functions, including (subject to para-*
 9 *graph (5)) functions under the Medicare Integ-*
 10 *rity Program under section 1893, as are nec-*
 11 *essary to carry out the purposes of this title.*

12 “(5) *RELATIONSHIP TO MIP CONTRACTS.—*

13 “(A) *NONDUPLICATION OF ACTIVITIES.—In*
 14 *entering into contracts under this section, the*
 15 *Secretary shall assure that activities of medicare*
 16 *administrative contractors do not duplicate ac-*
 17 *tivities carried out under contracts entered into*
 18 *under the Medicare Integrity Program under sec-*
 19 *tion 1893. The previous sentence shall not apply*
 20 *with respect to the activity described in section*
 21 *1893(b)(5) (relating to prior authorization of*
 22 *certain items of durable medical equipment*
 23 *under section 1834(a)(15)).*

24 “(B) *CONSTRUCTION.—An entity shall not*
 25 *be treated as a medicare administrative con-*

1 *tractor merely by reason of having entered into*
 2 *a contract with the Secretary under section*
 3 *1893.*

4 “(6) *APPLICATION OF FEDERAL ACQUISITION*
 5 *REGULATION.—Except to the extent inconsistent with*
 6 *a specific requirement of this title, the Federal Acqui-*
 7 *sition Regulation applies to contracts under this title.*

8 “(b) *CONTRACTING REQUIREMENTS.—*

9 “(1) *USE OF COMPETITIVE PROCEDURES.—*

10 “(A) *IN GENERAL.—Except as provided in*
 11 *laws with general applicability to Federal acqui-*
 12 *sition and procurement, the Federal Acquisition*
 13 *Regulation, or in subparagraph (B), the Sec-*
 14 *retary shall use competitive procedures when en-*
 15 *tering into contracts with medicare administra-*
 16 *tive contractors under this section.*

17 “(B) *RENEWAL OF CONTRACTS.—The Sec-*
 18 *retary may renew a contract with a medicare*
 19 *administrative contractor under this section*
 20 *from term to term without regard to section 5 of*
 21 *title 41, United States Code, or any other provi-*
 22 *sion of law requiring competition, if the medi-*
 23 *care administrative contractor has met or ex-*
 24 *ceeded the performance requirements applicable*
 25 *with respect to the contract and contractor, ex-*

cept that the Secretary shall provide for the application of competitive procedures under such a contract not less frequently than once every 6 years.

“(C) *TRANSFER OF FUNCTIONS.*—The Secretary may transfer functions among medicare administrative contractors without regard to any provision of law requiring competition. The Secretary shall ensure that performance quality is considered in such transfers. The Secretary shall provide notice (whether in the Federal Register or otherwise) of any such transfer (including a description of the functions so transferred and contact information for the contractors involved) to providers of services, physicians, practitioners, facilities, and suppliers affected by the transfer.

“(D) *INCENTIVES FOR QUALITY.*—The Secretary may provide incentives for medicare administrative contractors to provide quality service and to promote efficiency.

“(2) *COMPLIANCE WITH REQUIREMENTS.*—No contract under this section shall be entered into with any medicare administrative contractor unless the Secretary finds that such medicare administrative contractor will perform its obligations under the con-

1 *tract efficiently and effectively and will meet such re-*
 2 *quirements as to financial responsibility, legal au-*
 3 *thority, and other matters as the Secretary finds per-*
 4 *tinent.*

5 *“(3) PERFORMANCE REQUIREMENTS.—*

6 *“(A) DEVELOPMENT OF SPECIFIC PERFORM-*
 7 *ANCE REQUIREMENTS.—The Secretary shall de-*
 8 *velop contract performance requirements to carry*
 9 *out the specific requirements applicable under*
 10 *this title to a function described in subsection*
 11 *(a)(4) and shall develop standards for measuring*
 12 *the extent to which a contractor has met such re-*
 13 *quirements. In developing such performance re-*
 14 *quirements and standards for measurement, the*
 15 *Secretary shall consult with providers of services,*
 16 *organizations representative of beneficiaries*
 17 *under this title, and organizations and agencies*
 18 *performing functions necessary to carry out the*
 19 *purposes of this section with respect to such per-*
 20 *formance requirements. The Secretary shall make*
 21 *such performance requirements and measurement*
 22 *standards available to the public.*

23 *“(B) CONSIDERATIONS.—The Secretary*
 24 *shall include, as 1 of the standards, provider and*
 25 *beneficiary satisfaction levels.*

1 “(C) *INCLUSION IN CONTRACTS.*—All con-
 2 tractor performance requirements shall be set
 3 forth in the contract between the Secretary and
 4 the appropriate medicare administrative con-
 5 tractor. Such performance requirements—

6 “(i) shall reflect the performance re-
 7 quirements published under subparagraph
 8 (A), but may include additional perform-
 9 ance requirements;

10 “(ii) shall be used for evaluating con-
 11 tractor performance under the contract; and

12 “(iii) shall be consistent with the writ-
 13 ten statement of work provided under the
 14 contract.

15 “(4) *INFORMATION REQUIREMENTS.*—The Sec-
 16 retary shall not enter into a contract with a medicare
 17 administrative contractor under this section unless
 18 the contractor agrees—

19 “(A) to furnish to the Secretary such timely
 20 information and reports as the Secretary may
 21 find necessary in performing his functions under
 22 this title; and

23 “(B) to maintain such records and afford
 24 such access thereto as the Secretary finds nec-
 25 essary to assure the correctness and verification

1 *of the information and reports under subpara-*
 2 *graph (A) and otherwise to carry out the pur-*
 3 *poses of this title.*

4 “(5) *SURETY BOND.*—*A contract with a medi-*
 5 *care administrative contractor under this section may*
 6 *require the medicare administrative contractor, and*
 7 *any of its officers or employees certifying payments or*
 8 *disbursing funds pursuant to the contract, or other-*
 9 *wise participating in carrying out the contract, to*
 10 *give surety bond to the United States in such amount*
 11 *as the Secretary may deem appropriate.*

12 “(6) *RETAINING DIVERSITY OF LOCAL COVERAGE*
 13 *DETERMINATIONS.*—*A contract with a medicare ad-*
 14 *ministrative contractor under this section to perform*
 15 *the function of developing local coverage determina-*
 16 *tions (as defined in section 1869(f)(2)(B)) shall pro-*
 17 *vide that the contractor shall—*

18 “(A) *designate at least 1 different indi-*
 19 *vidual to serve as medical director for each State*
 20 *for which such contract performs such function;*

21 “(B) *utilize such medical director in the*
 22 *performance of such function; and*

23 “(C) *appoint a contractor advisory com-*
 24 *mittee with respect to each such State to provide*
 25 *a formal mechanism for physicians in the State*

1 *to be informed of, and participate in, the devel-*
 2 *opment of a local coverage determination in an*
 3 *advisory capacity.*

4 “(c) *TERMS AND CONDITIONS.*—

5 “(1) *IN GENERAL.*—Subject to subsection (a)(6),
 6 *a contract with any medicare administrative con-*
 7 *tractor under this section may contain such terms*
 8 *and conditions as the Secretary finds necessary or ap-*
 9 *propriate and may provide for advances of funds to*
 10 *the medicare administrative contractor for the mak-*
 11 *ing of payments by it under subsection (a)(4)(B).*

12 “(2) *PROHIBITION ON MANDATES FOR CERTAIN*
 13 *DATA COLLECTION.*—The Secretary may not require,
 14 *as a condition of entering into, or renewing, a con-*
 15 *tract under this section, that the medicare adminis-*
 16 *trative contractor match data obtained other than in*
 17 *its activities under this title with data used in the ad-*
 18 *ministration of this title for purposes of identifying*
 19 *situations in which the provisions of section 1862(b)*
 20 *may apply.*

21 “(d) *LIMITATION ON LIABILITY OF MEDICARE ADMIN-*
 22 *ISTRATIVE CONTRACTORS AND CERTAIN OFFICERS.*—

23 “(1) *CERTIFYING OFFICER.*—No individual des-
 24 *ignated pursuant to a contract under this section as*
 25 *a certifying officer shall, in the absence of the reckless*

1 *disregard of the individual's obligations or the intent*
 2 *by that individual to defraud the United States, be*
 3 *liable with respect to any payments certified by the*
 4 *individual under this section.*

5 *“(2) DISBURSING OFFICER.—No disbursing offi-*
 6 *cer shall, in the absence of the reckless disregard of the*
 7 *officer's obligations or the intent by that officer to de-*
 8 *fraud the United States, be liable with respect to any*
 9 *payment by such officer under this section if it was*
 10 *based upon an authorization (which meets the appli-*
 11 *cable requirements for such internal controls estab-*
 12 *lished by the Comptroller General) of a certifying offi-*
 13 *cer designated as provided in paragraph (1) of this*
 14 *subsection.*

15 *“(3) LIABILITY OF MEDICARE ADMINISTRATIVE*
 16 *CONTRACTOR.—No medicare administrative con-*
 17 *tractor shall be liable to the United States for a pay-*
 18 *ment by a certifying or disbursing officer unless, in*
 19 *connection with such a payment, the medicare ad-*
 20 *ministrative contractor acted with reckless disregard*
 21 *of its obligations under its medicare administrative*
 22 *contract or with intent to defraud the United States.*

23 *“(4) RELATIONSHIP TO FALSE CLAIMS ACT.—*
 24 *Nothing in this subsection shall be construed to limit*
 25 *liability for conduct that would constitute a violation*

1 of sections 3729 through 3731 of title 31, United
 2 States Code (commonly known as the “False Claims
 3 Act”).

4 “(5) INDEMNIFICATION BY SECRETARY.—

5 “(A) IN GENERAL.—Notwithstanding any
 6 other provision of law and subject to the suc-
 7 ceeding provisions of this paragraph, in the case
 8 of a medicare administrative contractor (or a
 9 person who is a director, officer, or employee of
 10 such a contractor or who is engaged by the con-
 11 tractor to participate directly in the claims ad-
 12 ministration process) who is made a party to
 13 any judicial or administrative proceeding aris-
 14 ing from, or relating directly to, the claims ad-
 15 ministration process under this title, the Sec-
 16 retary may, to the extent specified in the con-
 17 tract with the contractor, indemnify the con-
 18 tractor (and such persons).

19 “(B) CONDITIONS.—The Secretary may not
 20 provide indemnification under subparagraph (A)
 21 insofar as the liability for such costs arises di-
 22 rectly from conduct that is determined by the
 23 Secretary to be criminal in nature, fraudulent,
 24 or grossly negligent.

1 “(C) *SCOPE OF INDEMNIFICATION.*—Indem-
 2 *nification by the Secretary under subparagraph*
 3 *(A) may include payment of judgments, settle-*
 4 *ments (subject to subparagraph (D)), awards,*
 5 *and costs (including reasonable legal expenses).*

6 “(D) *WRITTEN APPROVAL FOR SETTLE-*
 7 *MENTS.*—*A contractor or other person described*
 8 *in subparagraph (A) may not propose to nego-*
 9 *tiate a settlement or compromise of a proceeding*
 10 *described in such subparagraph without the*
 11 *prior written approval of the Secretary to nego-*
 12 *tiate a settlement. Any indemnification under*
 13 *subparagraph (A) with respect to amounts paid*
 14 *under a settlement are conditioned upon the Sec-*
 15 *retary’s prior written approval of the final set-*
 16 *tlement.*

17 “(E) *CONSTRUCTION.*—*Nothing in this*
 18 *paragraph shall be construed—*

19 “(i) *to change any common law immu-*
 20 *nity that may be available to a medicare*
 21 *administrative contractor or person de-*
 22 *scribed in subparagraph (A); or*

23 “(ii) *to permit the payment of costs*
 24 *not otherwise allowable, reasonable, or allo-*

1 *cable under the Federal Acquisition Regula-*
 2 *tions.”.*

3 (2) *CONSIDERATION OF INCORPORATION OF CUR-*
 4 *RENT LAW STANDARDS.—In developing contract per-*
 5 *formance requirements under section 1874A(b) of the*
 6 *Social Security Act (as added by paragraph (1)) the*
 7 *Secretary shall consider inclusion of the performance*
 8 *standards described in sections 1816(f)(2) of such Act*
 9 *(relating to timely processing of reconsiderations and*
 10 *applications for exemptions) and section*
 11 *1842(b)(2)(B) of such Act (relating to timely review*
 12 *of determinations and fair hearing requests), as such*
 13 *sections were in effect before the date of enactment of*
 14 *this Act.*

15 (b) *CONFORMING AMENDMENTS TO SECTION 1816 (RE-*
 16 *LATING TO FISCAL INTERMEDIARIES).—Section 1816 (42*
 17 *U.S.C. 1395h) is amended as follows:*

18 (1) *The heading is amended to read as follows:*
 19 *“PROVISIONS RELATING TO THE ADMINISTRATION OF PART*
 20 *A”.*

21 (2) *Subsection (a) is amended to read as follows:*
 22 *“(a) The administration of this part shall be conducted*
 23 *through contracts with medicare administrative contractors*
 24 *under section 1874A.”.*

25 (3) *Subsection (b) is repealed.*

26 (4) *Subsection (c) is amended—*

1 “(a) *The administration of this part shall be conducted*
 2 *through contracts with medicare administrative contractors*
 3 *under section 1874A.*”.

4 (3) *Subsection (b) is amended—*

5 (A) *by striking paragraph (1);*

6 (B) *in paragraph (2)—*

7 (i) *by striking subparagraphs (A) and*
 8 *(B);*

9 (ii) *in subparagraph (C), by striking*
 10 *“carriers” and inserting “medicare admin-*
 11 *istrative contractors”; and*

12 (iii) *by striking subparagraphs (D)*
 13 *and (E);*

14 (C) *in paragraph (3)—*

15 (i) *in the matter before subparagraph*
 16 *(A), by striking “Each such contract shall*
 17 *provide that the carrier” and inserting*
 18 *“The Secretary”;*

19 (ii) *by striking “will” the first place it*
 20 *appears in each of subparagraphs (A), (B),*
 21 *(F), (G), (H), and (L) and inserting*
 22 *“shall”;*

23 (iii) *in subparagraph (B), in the mat-*
 24 *ter before clause (i), by striking “to the pol-*
 25 *icyholders and subscribers of the carrier”*

1 *and inserting “to the policyholders and sub-*
 2 *scribers of the medicare administrative con-*
 3 *tractor”;*

4 *(iv) by striking subparagraphs (C),*
 5 *(D), and (E);*

6 *(v) in subparagraph (H)—*

7 *(I) by striking “if it makes deter-*
 8 *minations or payments with respect to*
 9 *physicians’ services,”; and*

10 *(II) by striking “carrier” and in-*
 11 *serting “medicare administrative con-*
 12 *tractor”;*

13 *(vi) by striking subparagraph (I);*

14 *(vii) in subparagraph (L), by striking*
 15 *the semicolon and inserting a period;*

16 *(viii) in the first sentence, after sub-*
 17 *paragraph (L), by striking “and shall con-*
 18 *tain” and all that follows through the pe-*
 19 *riod; and*

20 *(ix) in the seventh sentence, by insert-*
 21 *ing “medicare administrative contractor,”*
 22 *after “carrier,”;*

23 *(D) by striking paragraph (5);*

1 (E) in paragraph (6)(D)(iv), by striking
2 “carrier” and inserting “medicare administra-
3 tive contractor”; and

4 (F) in paragraph (7), by striking “the car-
5 rier” and inserting “the Secretary” each place it
6 appears.

7 (4) Subsection (c) is amended—

8 (A) by striking paragraph (1);

9 (B) in paragraph (2), by striking “contract
10 under this section which provides for the dis-
11 bursement of funds, as described in subsection
12 (a)(1)(B),” and inserting “contract under section
13 1874A that provides for making payments under
14 this part”;

15 (C) in paragraph (3)(A), by striking “sub-
16 section (a)(1)(B)” and inserting “section
17 1874A(a)(3)(B)”;

18 (D) in paragraph (4), by striking “carrier”
19 and inserting “medicare administrative con-
20 tractor”;

21 (E) in paragraph (5), by striking “contract
22 under this section which provides for the dis-
23 bursement of funds, as described in subsection
24 (a)(1)(B), shall require the carrier” and “carrier
25 responses” and inserting “contract under section

1 1874A that provides for making payments under
 2 this part shall require the medicare administra-
 3 tive contractor” and “contractor responses”, re-
 4 spectively; and

5 (F) by striking paragraph (6).

6 (5) Subsections (d), (e), and (f) are repealed.

7 (6) Subsection (g) is amended by striking “car-
 8 rier or carriers” and inserting “medicare administra-
 9 tive contractor or contractors”.

10 (7) Subsection (h) is amended—

11 (A) in paragraph (2)—

12 (i) by striking “Each carrier having
 13 an agreement with the Secretary under sub-
 14 section (a)” and inserting “The Secretary”;
 15 and

16 (ii) by striking “Each such carrier”
 17 and inserting “The Secretary”;

18 (B) in paragraph (3)(A)—

19 (i) by striking “a carrier having an
 20 agreement with the Secretary under sub-
 21 section (a)” and inserting “medicare ad-
 22 ministrative contractor having a contract
 23 under section 1874A that provides for mak-
 24 ing payments under this part”; and

1 (ii) by striking “such carrier” and in-
 2 serting “such contractor”;

3 (C) in paragraph (3)(B)—

4 (i) by striking “a carrier” and insert-
 5 ing “a medicare administrative contractor”
 6 each place it appears; and

7 (ii) by striking “the carrier” and in-
 8 serting “the contractor” each place it ap-
 9 pears; and

10 (D) in paragraphs (5)(A) and (5)(B)(iii),
 11 by striking “carriers” and inserting “medicare
 12 administrative contractors” each place it ap-
 13 pears.

14 (8) Subsection (l) is amended—

15 (A) in paragraph (1)(A)(iii), by striking
 16 “carrier” and inserting “medicare administra-
 17 tive contractor”; and

18 (B) in paragraph (2), by striking “carrier”
 19 and inserting “medicare administrative con-
 20 tractor”.

21 (9) Subsection (p)(3)(A) is amended by striking
 22 “carrier” and inserting “medicare administrative
 23 contractor”.

24 (10) Subsection (q)(1)(A) is amended by striking
 25 “carrier”.

1 (d) *EFFECTIVE DATE; TRANSITION RULE.*—

2 (1) *EFFECTIVE DATE.*—

3 (A) *IN GENERAL.*—*Except as otherwise pro-*
 4 *vided in this subsection, the amendments made*
 5 *by this section shall take effect on October 1,*
 6 *2005, and the Secretary is authorized to take*
 7 *such steps before such date as may be necessary*
 8 *to implement such amendments on a timely*
 9 *basis.*

10 (B) *CONSTRUCTION FOR CURRENT CON-*
 11 *TRACTS.*—*Such amendments shall not apply to*
 12 *contracts in effect before the date specified under*
 13 *subparagraph (A) that continue to retain the*
 14 *terms and conditions in effect on such date (ex-*
 15 *cept as otherwise provided under this title, other*
 16 *than under this section) until such date as the*
 17 *contract is let out for competitive bidding under*
 18 *such amendments.*

19 (C) *DEADLINE FOR COMPETITIVE BID-*
 20 *DING.*—*The Secretary shall provide for the let-*
 21 *ting by competitive bidding of all contracts for*
 22 *functions of medicare administrative contractors*
 23 *for annual contract periods that begin on or*
 24 *after October 1, 2011.*

25 (2) *GENERAL TRANSITION RULES.*—

1 (A) *AUTHORITY TO CONTINUE TO ENTER*
 2 *INTO NEW AGREEMENTS AND CONTRACTS AND*
 3 *WAIVER OF PROVIDER NOMINATION PROVISIONS*
 4 *DURING TRANSITION.*—*Prior to the date specified*
 5 *in paragraph (1)(A), the Secretary may, con-*
 6 *sistent with subparagraph (B), continue to enter*
 7 *into agreements under section 1816 and con-*
 8 *tracts under section 1842 of the Social Security*
 9 *Act (42 U.S.C. 1395h, 1395u). The Secretary*
 10 *may enter into new agreements under section*
 11 *1816 during the time period without regard to*
 12 *any of the provider nomination provisions of*
 13 *such section.*

14 (B) *APPROPRIATE TRANSITION.*—*The Sec-*
 15 *retary shall take such steps as are necessary to*
 16 *provide for an appropriate transition from*
 17 *agreements under section 1816 and contracts*
 18 *under section 1842 of the Social Security Act (42*
 19 *U.S.C. 1395h, 1395u) to contracts under section*
 20 *1874A, as added by subsection (a)(1).*

21 (3) *AUTHORIZING CONTINUATION OF MIP ACTIVI-*
 22 *TIES UNDER CURRENT CONTRACTS AND AGREEMENTS*
 23 *AND UNDER TRANSITION CONTRACTS.*—*The provisions*
 24 *contained in the exception in section 1893(d)(2) of the*
 25 *Social Security Act (42 U.S.C. 1395ddd(d)(2)) shall*

1 *continue to apply notwithstanding the amendments*
 2 *made by this section, and any reference in such provi-*
 3 *sions to an agreement or contract shall be deemed to*
 4 *include agreements and contracts entered into pursu-*
 5 *ant to paragraph (2)(A).*

6 (e) *REFERENCES.*—*On and after the effective date pro-*
 7 *vided under subsection (d)(1), any reference to a fiscal*
 8 *intermediary or carrier under title XI or XVIII of the So-*
 9 *cial Security Act (or any regulation, manual instruction,*
 10 *interpretative rule, statement of policy, or guideline issued*
 11 *to carry out such titles) shall be deemed a reference to an*
 12 *appropriate medicare administrative contractor (as pro-*
 13 *vided under section 1874A of the Social Security Act).*

14 (f) *SECRETARIAL SUBMISSION OF LEGISLATIVE PRO-*
 15 *POSAL.*—*Not later than 6 months after the date of enact-*
 16 *ment of this Act, the Secretary shall submit to the appro-*
 17 *priate committees of Congress a legislative proposal pro-*
 18 *viding for such technical and conforming amendments in*
 19 *the law as are required by the provisions of this section.*

20 (g) *REPORTS ON IMPLEMENTATION.*—

21 (1) *PROPOSAL FOR IMPLEMENTATION.*—*At least*
 22 *1 year before the date specified in subsection*
 23 *(d)(1)(A), the Secretary shall submit a report to Con-*
 24 *gress and the Comptroller General of the United*
 25 *States that describes a plan for an appropriate tran-*

1 *sition. The Comptroller General shall conduct an*
2 *evaluation of such plan and shall submit to Congress,*
3 *not later than 6 months after the date the report is*
4 *received, a report on such evaluation and shall in-*
5 *clude in such report such recommendations as the*
6 *Comptroller General deems appropriate.*

7 (2) *STATUS OF IMPLEMENTATION.—The Sec-*
8 *retary shall submit a report to Congress not later*
9 *than October 1, 2008, that describes the status of im-*
10 *plementation of such amendments and that includes*
11 *a description of the following:*

12 (A) *The number of contracts that have been*
13 *competitively bid as of such date.*

14 (B) *The distribution of functions among*
15 *contracts and contractors.*

16 (C) *A timeline for complete transition to*
17 *full competition.*

18 (D) *A detailed description of how the Sec-*
19 *retary has modified oversight and management*
20 *of medicare contractors to adapt to full competi-*
21 *tion.*

**Subtitle D—Education and
Outreach Improvements**

**SEC. 531. PROVIDER EDUCATION AND TECHNICAL ASSIST-
ANCE.**

(a) COORDINATION OF EDUCATION FUNDING.—

(1) IN GENERAL.—The Social Security Act is amended by inserting after section 1888 the following new section:

“PROVIDER EDUCATION AND TECHNICAL ASSISTANCE

*“SEC. 1889. (a) COORDINATION OF EDUCATION FUND-
ING.—The Secretary shall coordinate the educational activi-
ties provided through medicare contractors (as defined in
subsection (e), including under section 1893) in order to
maximize the effectiveness of Federal education efforts for
providers of services, physicians, practitioners, and sup-
pliers.”.*

*(2) EFFECTIVE DATE.—The amendment made by
paragraph (1) shall take effect on the date of enact-
ment of this Act.*

*(b) INCENTIVES TO IMPROVE CONTRACTOR PERFORM-
ANCE.—*

*(1) IN GENERAL.—Section 1874A, as added by
section 521(a)(1), is amended by adding at the end
the following new subsection:*

1 “(e) *INCENTIVES TO IMPROVE CONTRACTOR PERFORM-*
 2 *ANCE IN PROVIDER EDUCATION AND OUTREACH.*—

3 “(1) *METHODOLOGY TO MEASURE CONTRACTOR*
 4 *ERROR RATES.*—*In order to give medicare contractors*
 5 *(as defined in paragraph (3)) an incentive to imple-*
 6 *ment effective education and outreach programs for*
 7 *providers of services, physicians, practitioners, and*
 8 *suppliers, the Secretary shall develop and implement*
 9 *by October 1, 2004, a methodology to measure the spe-*
 10 *cific claims payment error rates of such contractors*
 11 *in the processing or reviewing of medicare claims.*

12 “(2) *GAO REVIEW OF METHODOLOGY.*—*The*
 13 *Comptroller General of the United States shall review,*
 14 *and make recommendations to the Secretary, regard-*
 15 *ing the adequacy of such methodology.*

16 “(3) *MEDICARE CONTRACTOR DEFINED.*—*For*
 17 *purposes of this subsection, the term ‘medicare con-*
 18 *tractor’ includes a medicare administrative con-*
 19 *tractor, a fiscal intermediary with a contract under*
 20 *section 1816, and a carrier with a contract under sec-*
 21 *tion 1842.’.*

22 “(2) *REPORT.*—*The Secretary shall submit to*
 23 *Congress a report that describes how the Secretary in-*
 24 *tends to use the methodology developed under section*
 25 *1874A(e)(1) of the Social Security Act, as added by*

1 *paragraph (1), in assessing medicare contractor per-*
 2 *formance in implementing effective education and*
 3 *outreach programs, including whether to use such*
 4 *methodology as a basis for performance bonuses.*

5 *(c) IMPROVED PROVIDER EDUCATION AND TRAIN-*
 6 *ING.—*

7 *(1) INCREASED FUNDING FOR ENHANCED EDU-*
 8 *CATION AND TRAINING THROUGH MEDICARE INTEG-*
 9 *RITY PROGRAM.—Section 1817(k)(4) (42 U.S.C.*
 10 *1395i(k)(4)) is amended—*

11 *(A) in subparagraph (A), by striking “sub-*
 12 *paragraph (B)” and inserting “subparagraphs*
 13 *(B) and (C)”;*

14 *(B) in subparagraph (B), by striking “The*
 15 *amount appropriated” and inserting “Subject to*
 16 *subparagraph (C), the amount appropriated”;*
 17 *and*

18 *(C) by adding at the end the following new*
 19 *subparagraph:*

20 *“(C) ENHANCED PROVIDER EDUCATION AND*
 21 *TRAINING.—*

22 *“(i) IN GENERAL.—In addition to the*
 23 *amount appropriated under subparagraph*
 24 *(B), the amount appropriated under sub-*
 25 *paragraph (A) for a fiscal year (beginning*

with fiscal year 2004) is increased by
\$35,000,000.

“(ii) *USE.*—The funds made available
under this subparagraph shall be used only
to increase the conduct by medicare contrac-
tors of education and training of providers
of services, physicians, practitioners, and
suppliers regarding billing, coding, and
other appropriate items and may also be
used to improve the accuracy, consistency,
and timeliness of contractor responses to
written and phone inquiries from providers
of services, physicians, practitioners, and
suppliers.”.

(2) *TAILORING EDUCATION AND TRAINING FOR
SMALL PROVIDERS OR SUPPLIERS.*—

(A) *IN GENERAL.*—Section 1889, as added
by subsection (a), is amended by adding at the
end the following new subsection:

“(b) *TAILORING EDUCATION AND TRAINING ACTIVI-
TIES FOR SMALL PROVIDERS OR SUPPLIERS.*—

“(1) *IN GENERAL.*—Insofar as a medicare con-
tractor conducts education and training activities, it
shall take into consideration the special needs of small
providers of services or suppliers (as defined in para-

graph (2)). Such education and training activities for small providers of services and suppliers may include the provision of technical assistance (such as review of billing systems and internal controls to determine program compliance and to suggest more efficient and effective means of achieving such compliance).

“(2) *SMALL PROVIDER OF SERVICES OR SUPPLIER.*—In this subsection, the term ‘small provider of services or supplier’ means—

“(A) an institutional provider of services with fewer than 25 full-time-equivalent employees; or

“(B) a physician, practitioner, or supplier with fewer than 10 full-time-equivalent employees.”.

(B) *EFFECTIVE DATE.*—The amendment made by subparagraph (A) shall take effect on January 1, 2004.

(d) *ADDITIONAL PROVIDER EDUCATION PROVISIONS.*—

(1) *IN GENERAL.*—Section 1889, as added by subsection (a) and as amended by subsection (c)(2), is amended by adding at the end the following new subsections:

1 “(c) *ENCOURAGEMENT OF PARTICIPATION IN EDU-*
 2 *CATION PROGRAM ACTIVITIES.*—A medicare contractor
 3 *may not use a record of attendance at (or failure to attend)*
 4 *educational activities or other information gathered during*
 5 *an educational program conducted under this section or*
 6 *otherwise by the Secretary to select or track providers of*
 7 *services, physicians, practitioners, or suppliers for the pur-*
 8 *pose of conducting any type of audit or prepayment review.*

9 “(d) *CONSTRUCTION.*—Nothing in this section or sec-
 10 *tion 1893(g) shall be construed as providing for disclosure*
 11 *by a medicare contractor—*

12 “(1) *of the screens used for identifying claims*
 13 *that will be subject to medical review; or*

14 “(2) *of information that would compromise*
 15 *pending law enforcement activities or reveal findings*
 16 *of law enforcement-related audits.*

17 “(e) *DEFINITIONS.*—For purposes of this section and
 18 *section 1817(k)(4)(C), the term ‘medicare contractor’ in-*
 19 *cludes the following:*

20 “(1) *A medicare administrative contractor with*
 21 *a contract under section 1874A, a fiscal intermediary*
 22 *with a contract under section 1816, and a carrier*
 23 *with a contract under section 1842.*

24 “(2) *An eligible entity with a contract under sec-*
 25 *tion 1893.*

1 *Such term does not include, with respect to activities of a*
 2 *specific provider of services, physician, practitioner, or sup-*
 3 *plier an entity that has no authority under this title or*
 4 *title XI with respect to such activities and such provider*
 5 *of services, physician, practitioner, or supplier.”.*

6 (2) *EFFECTIVE DATE.*—*The amendment made by*
 7 *paragraph (1) shall take effect on the date of enact-*
 8 *ment of this Act.*

9 **SEC. 532. ACCESS TO AND PROMPT RESPONSES FROM MEDI-**
 10 **CARE CONTRACTORS.**

11 (a) *IN GENERAL.*—*Section 1874A, as added by section*
 12 *521(a)(1) and as amended by section 531(b)(1), is amended*
 13 *by adding at the end the following new subsection:*

14 “(f) *COMMUNICATING WITH BENEFICIARIES AND PRO-*
 15 *VIDERS.*—

16 “(1) *COMMUNICATION PROCESS.*—*The Secretary*
 17 *shall develop a process for medicare contractors to*
 18 *communicate with beneficiaries and with providers of*
 19 *services, physicians, practitioners, and suppliers*
 20 *under this title.*

21 “(2) *RESPONSE TO WRITTEN INQUIRIES.*—*Each*
 22 *medicare contractor (as defined in paragraph (5))*
 23 *shall provide general written responses (which may be*
 24 *through electronic transmission) in a clear, concise,*
 25 *and accurate manner to inquiries by beneficiaries,*

1 providers of services, physicians, practitioners, and
 2 suppliers concerning the programs under this title
 3 within 45 business days of the date of receipt of such
 4 inquiries.

5 “(3) *RESPONSE TO TOLL-FREE LINES.*—The Sec-
 6 retary shall ensure that medicare contractors provide
 7 a toll-free telephone number at which beneficiaries,
 8 providers, physicians, practitioners, and suppliers
 9 may obtain information regarding billing, coding,
 10 claims, coverage, and other appropriate information
 11 under this title.

12 “(4) *MONITORING OF CONTRACTOR RE-*
 13 *SPONSES.*—

14 “(A) *IN GENERAL.*—Each medicare con-
 15 tractor shall, consistent with standards developed
 16 by the Secretary under subparagraph (B)—

17 “(i) maintain a system for identifying
 18 who provides the information referred to in
 19 paragraphs (2) and (3); and

20 “(ii) monitor the accuracy, consist-
 21 ency, and timeliness of the information so
 22 provided.

23 “(B) *DEVELOPMENT OF STANDARDS.*—

24 “(i) *IN GENERAL.*—The Secretary shall
 25 establish (and publish in the Federal Reg-

1 *ister) standards regarding the accuracy,*
2 *consistency, and timeliness of the informa-*
3 *tion provided in response to inquiries under*
4 *this subsection. Such standards shall be con-*
5 *sistent with the performance requirements*
6 *established under subsection (b)(3).*

7 “(ii) *EVALUATION.*—*In conducting*
8 *evaluations of individual medicare contrac-*
9 *tors, the Secretary shall consider the results*
10 *of the monitoring conducted under subpara-*
11 *graph (A) taking into account as perform-*
12 *ance requirements the standards established*
13 *under clause (i). The Secretary shall, in*
14 *consultation with organizations rep-*
15 *resenting providers of services, suppliers,*
16 *and individuals entitled to benefits under*
17 *part A or enrolled under part B, or both, es-*
18 *tablish standards relating to the accuracy,*
19 *consistency, and timeliness of the informa-*
20 *tion so provided.*

21 “(C) *DIRECT MONITORING.*—*Nothing in this*
22 *paragraph shall be construed as preventing the*
23 *Secretary from directly monitoring the accuracy,*
24 *consistency, and timeliness of the information so*
25 *provided.*

1 “(5) *MEDICARE CONTRACTOR DEFINED.*—*For*
 2 *purposes of this subsection, the term ‘medicare con-*
 3 *tractor’ has the meaning given such term in sub-*
 4 *section (e)(3).’.*”

5 (b) *EFFECTIVE DATE.*—*The amendment made by sub-*
 6 *section (a) shall take effect October 1, 2004.*

7 (c) *AUTHORIZATION OF APPROPRIATIONS.*—*There are*
 8 *authorized to be appropriated such sums as are necessary*
 9 *to carry out section 1874A(f) of the Social Security Act,*
 10 *as added by subsection (a).*

11 **SEC. 533. RELIANCE ON GUIDANCE.**

12 (a) *IN GENERAL.*—*Section 1871(d), as added by sec-*
 13 *tion 502(a), is amended by adding at the end the following*
 14 *new paragraph:*

15 “(2) *If—*

16 “(A) *a provider of services, physician, practi-*
 17 *tioner, or other supplier follows written guidance*
 18 *provided—*

19 “(i) *by the Secretary; or*

20 “(ii) *by a medicare contractor (as defined*
 21 *in section 1889(e) and whether in the form of a*
 22 *written response to a written inquiry under sec-*
 23 *tion 1874A(f)(1) or otherwise) acting within the*
 24 *scope of the contractor’s contract authority,*

1 *in response to a written inquiry with respect to the*
2 *furnishing of items or services or the submission of a*
3 *claim for benefits for such items or services;*

4 “(B) the Secretary determines that—

5 “(i) the provider of services, physician,
6 practitioner, or supplier has accurately presented
7 the circumstances relating to such items, services,
8 and claim to the Secretary or the contractor in
9 the written guidance; and

10 “(ii) there is no indication of fraud or
11 abuse committed by the provider of services, phy-
12 sician, practitioner, or supplier against the pro-
13 gram under this title; and

14 “(C) the guidance was in error;
15 *the provider of services, physician, practitioner, or supplier*
16 *shall not be subject to any penalty or interest under this*
17 *title (or the provisions of title XI insofar as they relate to*
18 *this title) relating to the provision of such items or service*
19 *or such claim if the provider of services, physician, practi-*
20 *tioner, or supplier reasonably relied on such guidance. In*
21 *applying this paragraph with respect to guidance in the*
22 *form of general responses to frequently asked questions, the*
23 *Secretary retains authority to determine the extent to which*
24 *such general responses apply to the particular cir-*
25 *cumstances of individual claims.”.*

1 (b) *EFFECTIVE DATE.*—*The amendment made by sub-*
 2 *section (a) shall apply to penalties imposed on or after the*
 3 *date of enactment of this Act.*

4 **SEC. 534. MEDICARE PROVIDER OMBUDSMAN.**

5 (a) *MEDICARE PROVIDER OMBUDSMAN.*—*Section 1868*
 6 *(42 U.S.C. 1395ee) is amended—*

7 (1) *by adding at the end of the heading the fol-*
 8 *lowing: “; MEDICARE PROVIDER OMBUDSMAN”;*

9 (2) *by inserting “PRACTICING PHYSICIANS ADVI-*
 10 *SORY COUNCIL.—(1)” after “(a)”;*

11 (3) *in paragraph (1), as so redesignated under*
 12 *paragraph (2), by striking “in this section” and in-*
 13 *serting “in this subsection”;*

14 (4) *by redesignating subsections (b) and (c) as*
 15 *paragraphs (2) and (3), respectively; and*

16 (5) *by adding at the end the following new sub-*
 17 *section:*

18 “(b) *MEDICARE PROVIDER OMBUDSMAN.*—

19 “(1) *IN GENERAL.*—*By not later than 1 year*
 20 *after the date of enactment of the Prescription Drug*
 21 *and Medicare Improvement Act of 2003, the Secretary*
 22 *shall appoint a Medicare Provider Ombudsman.*

23 “(2) *DUTIES.*—*The Medicare Provider Ombuds-*
 24 *man shall—*

1 “(A) provide assistance, on a confidential
2 basis, to entities and individuals providing items
3 and services, including covered drugs under part
4 D, under this title with respect to complaints,
5 grievances, and requests for information con-
6 cerning the programs under this title (including
7 provisions of title XI insofar as they relate to
8 this title and are not administered by the Office
9 of the Inspector General of the Department of
10 Health and Human Services) and in the resolu-
11 tion of unclear or conflicting guidance given by
12 the Secretary and medicare contractors to such
13 providers of services and suppliers regarding
14 such programs and provisions and requirements
15 under this title and such provisions; and

16 “(B) submit recommendations to the Sec-
17 retary for improvement in the administration of
18 this title and such provisions, including—

19 “(i) recommendations to respond to re-
20 curring patterns of confusion in this title
21 and such provisions (including rec-
22 ommendations regarding suspending im-
23 position of sanctions where there is wide-
24 spread confusion in program administra-
25 tion), and

1 “(ii) recommendations to provide for
 2 an appropriate and consistent response (in-
 3 cluding not providing for audits) in cases of
 4 self-identified overpayments by providers of
 5 services and suppliers.

6 “(3) *STAFF.*—The Secretary shall provide the
 7 Medicare Provider Ombudsman with appropriate
 8 staff.”.

9 (b) *FUNDING.*—There are authorized to be appro-
 10 priated to the Secretary (in appropriate part from the Fed-
 11 eral Hospital Insurance Trust Fund and the Federal Sup-
 12 plementary Medical Insurance Trust Fund (including the
 13 Prescription Drug Account)) to carry out the provisions of
 14 subsection (b) of section 1868 of the Social Security Act
 15 (42 U.S.C. 1395ee) (relating to the Medicare Provider Om-
 16 budsman), as added by subsection (a)(5), such sums as are
 17 necessary for fiscal year 2004 and each succeeding fiscal
 18 year.

19 **SEC. 535. BENEFICIARY OUTREACH DEMONSTRATION PRO-**
 20 **GRAMS.**

21 (a) *DEMONSTRATION ON THE PROVISION OF ADVICE*
 22 *AND ASSISTANCE TO MEDICARE BENEFICIARIES AT LOCAL*
 23 *OFFICES OF THE SOCIAL SECURITY ADMINISTRATION.*—

24 (1) *ESTABLISHMENT.*—The Secretary shall estab-
 25 lish a demonstration program (in this subsection re-

ferred to as the “demonstration program”) under which medicare specialists employed by the Department of Health and Human Services provide advice and assistance to medicare beneficiaries at the location of existing local offices of the Social Security Administration.

(2) *LOCATIONS.—*

(A) *IN GENERAL.—*The demonstration program shall be conducted in at least 6 offices or areas. Subject to subparagraph (B), in selecting such offices and areas, the Secretary shall provide preference for offices with a high volume of visits by medicare beneficiaries.

(B) *ASSISTANCE FOR RURAL BENEFICIARIES.—*The Secretary shall provide for the selection of at least 2 rural areas to participate in the demonstration program. In conducting the demonstration program in such rural areas, the Secretary shall provide for medicare specialists to travel among local offices in a rural area on a scheduled basis.

(3) *DURATION.—*The demonstration program shall be conducted over a 3-year period.

(4) *EVALUATION AND REPORT.—*

1 (A) *EVALUATION.*—*The Secretary shall pro-*
 2 *vide for an evaluation of the demonstration pro-*
 3 *gram. Such evaluation shall include an analysis*
 4 *of—*

5 *(i) utilization of, and beneficiary satis-*
 6 *faction with, the assistance provided under*
 7 *the program; and*

8 *(ii) the cost-effectiveness of providing*
 9 *beneficiary assistance through out-sta-*
 10 *tioning medicare specialists at local social*
 11 *security offices.*

12 (B) *REPORT.*—*The Secretary shall submit*
 13 *to Congress a report on such evaluation and*
 14 *shall include in such report recommendations re-*
 15 *garding the feasibility of permanently out-sta-*
 16 *tioning Medicare specialists at local social secu-*
 17 *rity offices.*

18 (b) *DEMONSTRATION ON PROVIDING PRIOR DETER-*
 19 *MINATIONS.*—

20 (1) *ESTABLISHMENT.*—*By not later than 1 year*
 21 *after the date of enactment of this Act, the Secretary*
 22 *shall establish a demonstration project to test the ad-*
 23 *ministrative feasibility of providing a process for*
 24 *medicare beneficiaries and entities and individuals*
 25 *furnishing such beneficiaries with items and services*

1 *under title XVIII of the Social Security Act program*
 2 *to make a request for, and receive, a determination*
 3 *(after an advance beneficiary notice is issued with re-*
 4 *spect to the item or service involved but before such*
 5 *item or service is furnished to the beneficiary) as to*
 6 *whether the item or service is covered under such title*
 7 *consistent with the applicable requirements of section*
 8 *1862(a)(1)(A) of such Act (42 U.S.C. 1395y(a)(1)(A))*
 9 *(relating to medical necessity).*

10 (2) *EVALUATION AND REPORT.*—

11 (A) *EVALUATION.*—*The Secretary shall pro-*
 12 *vide for an evaluation of the demonstration pro-*
 13 *gram conducted under paragraph (1).*

14 (B) *REPORT.*—*By not later than January*
 15 *1, 2006, the Secretary shall submit to Congress*
 16 *a report on such evaluation together with rec-*
 17 *ommendations for such legislation and adminis-*
 18 *trative actions as the Secretary considers appro-*
 19 *priate.*

20 ***Subtitle E—Review, Recovery, and***
 21 ***Enforcement Reform***

22 ***SEC. 541. PREPAYMENT REVIEW.***

23 (a) *IN GENERAL.*—*Section 1874A, as added by section*
 24 *521(a)(1) and as amended by sections 531(b)(1) and*

1 532(a), is amended by adding at the end the following new
 2 subsection:

3 “(g) *CONDUCT OF PREPAYMENT REVIEW.*—

4 “(1) *STANDARDIZATION OF RANDOM PREPAY-*
 5 *MENT REVIEW.*—A medicare administrative con-
 6 tractor shall conduct random prepayment review only
 7 in accordance with a standard protocol for random
 8 prepayment audits developed by the Secretary.

9 “(2) *LIMITATIONS ON INITIATION OF NONRANDOM*
 10 *PREPAYMENT REVIEW.*—A medicare administrative
 11 contractor may not initiate nonrandom prepayment
 12 review of a provider of services, physician, practi-
 13 tioner, or supplier based on the initial identification
 14 by that provider of services, physician, practitioner,
 15 or supplier of an improper billing practice unless
 16 there is a likelihood of sustained or high level of pay-
 17 ment error (as defined by the Secretary).

18 “(3) *TERMINATION OF NONRANDOM PREPAYMENT*
 19 *REVIEW.*—The Secretary shall establish protocols or
 20 standards relating to the termination, including ter-
 21 mination dates, of nonrandom prepayment review.
 22 Such regulations may vary such a termination date
 23 based upon the differences in the circumstances trig-
 24 gering prepayment review.

1 “(4) *CONSTRUCTION.*—*Nothing in this subsection*
 2 *shall be construed as preventing the denial of pay-*
 3 *ments for claims actually reviewed under a random*
 4 *prepayment review. In the case of a provider of serv-*
 5 *ices, physician, practitioner, or supplier with respect*
 6 *to which amounts were previously overpaid, nothing*
 7 *in this subsection shall be construed as limiting the*
 8 *ability of a medicare administrative contractor to re-*
 9 *quest the periodic production of records or supporting*
 10 *documentation for a limited sample of submitted*
 11 *claims to ensure that the previous practice is not con-*
 12 *tinuing.*

13 “(5) *RANDOM PREPAYMENT REVIEW DEFINED.*—
 14 *For purposes of this subsection, the term ‘random pre-*
 15 *payment review’ means a demand for the production*
 16 *of records or documentation absent cause with respect*
 17 *to a claim.”.*

18 (b) *EFFECTIVE DATE.*—

19 (1) *IN GENERAL.*—*Except as provided in this*
 20 *subsection, the amendment made by subsection (a)*
 21 *shall take effect on the date of enactment of this Act.*

22 (2) *DEADLINE FOR PROMULGATION OF CERTAIN*
 23 *REGULATIONS.*—*The Secretary shall first issue regula-*
 24 *tions under section 1874A(g) of the Social Security*

1 *Act, as added by subsection (a), by not later than 1*
 2 *year after the date of enactment of this Act.*

3 (3) *APPLICATION OF STANDARD PROTOCOLS FOR*
 4 *RANDOM PREPAYMENT REVIEW.—Section 1874A(g)(1)*
 5 *of the Social Security Act, as added by subsection (a),*
 6 *shall apply to random prepayment reviews conducted*
 7 *on or after such date (not later than 1 year after the*
 8 *date of enactment of this Act) as the Secretary shall*
 9 *specify. The Secretary shall develop and publish the*
 10 *standard protocol under such section by not later*
 11 *than 1 year after the date of enactment of this Act.*

12 **SEC. 542. RECOVERY OF OVERPAYMENTS.**

13 (a) *IN GENERAL.—Section 1874A, as added by section*
 14 *521(a)(1) and as amended by sections 531(b)(1), 532(a),*
 15 *and 541(a), is amended by adding at the end the following*
 16 *new subsection:*

17 “(h) *RECOVERY OF OVERPAYMENTS.—*

18 “(1) *USE OF REPAYMENT PLANS.—*

19 “(A) *IN GENERAL.—If the repayment, with-*
 20 *in the period otherwise permitted by a provider*
 21 *of services, physician, practitioner, or other sup-*
 22 *plier, of an overpayment under this title meets*
 23 *the standards developed under subparagraph (B),*
 24 *subject to subparagraph (C), and the provider,*
 25 *physician, practitioner, or supplier requests the*

1 *Secretary to enter into a repayment plan with*
2 *respect to such overpayment, the Secretary shall*
3 *enter into a plan with the provider, physician,*
4 *practitioner, or supplier for the offset or repay-*
5 *ment (at the election of the provider, physician,*
6 *practitioner, or supplier) of such overpayment*
7 *over a period of at least 1 year, but not longer*
8 *than 3 years. Interest shall accrue on the balance*
9 *through the period of repayment. The repayment*
10 *plan shall meet terms and conditions determined*
11 *to be appropriate by the Secretary.*

12 *“(B) DEVELOPMENT OF STANDARDS.—The*
13 *Secretary shall develop standards for the recov-*
14 *ery of overpayments. Such standards shall—*

15 *“(i) include a requirement that the*
16 *Secretary take into account (and weigh in*
17 *favor of the use of a repayment plan) the*
18 *reliance (as described in section 1871(d)(2))*
19 *by a provider of services, physician, practi-*
20 *tioner, and supplier on guidance when de-*
21 *termining whether a repayment plan should*
22 *be offered; and*

23 *“(ii) provide for consideration of the*
24 *financial hardship imposed on a provider of*

1 *services, physician, practitioner, or supplier*
 2 *in considering such a repayment plan.*

3 *In developing standards with regard to financial*
 4 *hardship with respect to a provider of services,*
 5 *physician, practitioner, or supplier, the Sec-*
 6 *retary shall take into account the amount of the*
 7 *proposed recovery as a proportion of payments*
 8 *made to that provider, physician, practitioner,*
 9 *or supplier.*

10 “(C) *EXCEPTIONS.—Subparagraph (A)*
 11 *shall not apply if—*

12 “(i) *the Secretary has reason to suspect*
 13 *that the provider of services, physician,*
 14 *practitioner, or supplier may file for bank-*
 15 *ruptcy or otherwise cease to do business or*
 16 *discontinue participation in the program*
 17 *under this title; or*

18 “(ii) *there is an indication of fraud or*
 19 *abuse committed against the program.*

20 “(D) *IMMEDIATE COLLECTION IF VIOLATION*
 21 *OF REPAYMENT PLAN.—If a provider of services,*
 22 *physician, practitioner, or supplier fails to make*
 23 *a payment in accordance with a repayment plan*
 24 *under this paragraph, the Secretary may imme-*
 25 *diately seek to offset or otherwise recover the total*

1 *balance outstanding (including applicable inter-*
 2 *est) under the repayment plan.*

3 “(E) *RELATION TO NO FAULT PROVISION.*—
 4 *Nothing in this paragraph shall be construed as*
 5 *affecting the application of section 1870(c) (re-*
 6 *lating to no adjustment in the cases of certain*
 7 *overpayments).*

8 “(2) *LIMITATION ON RECOUPMENT.*—

9 “(A) *NO RECOUPMENT UNTIL RECONSIDER-*
 10 *ATION EXERCISED.*—*In the case of a provider of*
 11 *services, physician, practitioner, or supplier that*
 12 *is determined to have received an overpayment*
 13 *under this title and that seeks a reconsideration*
 14 *of such determination by a qualified independent*
 15 *contractor under section 1869(c), the Secretary*
 16 *may not take any action (or authorize any other*
 17 *person, including any Medicare contractor, as*
 18 *defined in subparagraph (C)) to recoup the over-*
 19 *payment until the date the decision on the recon-*
 20 *sideration has been rendered.*

21 “(B) *PAYMENT OF INTEREST.*—

22 “(i) *RETURN OF RECOUPED AMOUNT*
 23 *WITH INTEREST IN CASE OF REVERSAL.*—
 24 *Insofar as such determination on appeal*
 25 *against the provider of services, physician,*

1 *practitioner, or supplier is later reversed,*
 2 *the Secretary shall provide for repayment of*
 3 *the amount recouped plus interest for the*
 4 *period in which the amount was recouped.*

5 “(ii) *INTEREST IN CASE OF AFFIRMA-*
 6 *TION.—Insofar as the determination on*
 7 *such appeal is against the provider of serv-*
 8 *ices, physician, practitioner, or supplier,*
 9 *interest on the overpayment shall accrue on*
 10 *and after the date of the original notice of*
 11 *overpayment.*

12 “(iii) *RATE OF INTEREST.—The rate of*
 13 *interest under this subparagraph shall be*
 14 *the rate otherwise applicable under this title*
 15 *in the case of overpayments.*

16 “(C) *MEDICARE CONTRACTOR DEFINED.—*
 17 *For purposes of this subsection, the term ‘medi-*
 18 *care contractor’ has the meaning given such term*
 19 *in section 1889(e).*

20 “(3) *PAYMENT AUDITS.—*

21 “(A) *WRITTEN NOTICE FOR POST-PAYMENT*
 22 *AUDITS.—Subject to subparagraph (C), if a*
 23 *medicare contractor decides to conduct a post-*
 24 *payment audit of a provider of services, physi-*
 25 *cian, practitioner, or supplier under this title,*

1 *the contractor shall provide the provider of serv-*
 2 *ices, physician, practitioner, or supplier with*
 3 *written notice (which may be in electronic form)*
 4 *of the intent to conduct such an audit.*

5 *“(B) EXPLANATION OF FINDINGS FOR ALL*
 6 *AUDITS.—Subject to subparagraph (C), if a*
 7 *medicare contractor audits a provider of services,*
 8 *physician, practitioner, or supplier under this*
 9 *title, the contractor shall—*

10 *“(i) give the provider of services, phy-*
 11 *sician, practitioner, or supplier a full re-*
 12 *view and explanation of the findings of the*
 13 *audit in a manner that is understandable*
 14 *to the provider of services, physician, prac-*
 15 *titioner, or supplier and permits the devel-*
 16 *opment of an appropriate corrective action*
 17 *plan;*

18 *“(ii) inform the provider of services,*
 19 *physician, practitioner, or supplier of the*
 20 *appeal rights under this title as well as con-*
 21 *sent settlement options (which are at the*
 22 *discretion of the Secretary); and*

23 *“(iii) give the provider of services, phy-*
 24 *sician, practitioner, or supplier an oppor-*

1 tunity to provide additional information to
2 the contractor.

3 “(C) *EXCEPTION.*—Subparagraphs (A) and
4 (B) shall not apply if the provision of notice or
5 findings would compromise pending law enforce-
6 ment activities, whether civil or criminal, or re-
7 veal findings of law enforcement-related audits.

8 “(4) *NOTICE OF OVER-UTILIZATION OF CODES.*—
9 The Secretary shall establish, in consultation with or-
10 ganizations representing the classes of providers of
11 services, physicians, practitioners, and suppliers, a
12 process under which the Secretary provides for notice
13 to classes of providers of services, physicians, practi-
14 tioners, and suppliers served by a medicare contractor
15 in cases in which the contractor has identified that
16 particular billing codes may be overutilized by that
17 class of providers of services, physicians, practi-
18 tioners, or suppliers under the programs under this
19 title (or provisions of title XI insofar as they relate
20 to such programs).

21 “(5) *STANDARD METHODOLOGY FOR PROBE SAM-*
22 *PLING.*—The Secretary shall establish a standard
23 methodology for medicare administrative contractors
24 to use in selecting a sample of claims for review in
25 the case of an abnormal billing pattern.

1 “(6) *CONSENT SETTLEMENT REFORMS.*—

2 “(A) *IN GENERAL.*—*The Secretary may use*
 3 *a consent settlement (as defined in subparagraph*
 4 *(D)) to settle a projected overpayment.*

5 “(B) *OPPORTUNITY TO SUBMIT ADDITIONAL*
 6 *INFORMATION BEFORE CONSENT SETTLEMENT*
 7 *OFFER.*—*Before offering a provider of services,*
 8 *physician, practitioner, or supplier a consent*
 9 *settlement, the Secretary shall—*

10 “(i) *communicate to the provider of*
 11 *services, physician, practitioner, or supplier*
 12 *in a nonthreatening manner that, based on*
 13 *a review of the medical records requested by*
 14 *the Secretary, a preliminary evaluation of*
 15 *those records indicates that there would be*
 16 *an overpayment; and*

17 “(ii) *provide for a 45-day period dur-*
 18 *ing which the provider of services, physi-*
 19 *cian, practitioner, or supplier may furnish*
 20 *additional information concerning the med-*
 21 *ical records for the claims that had been re-*
 22 *viewed.*

23 “(C) *CONSENT SETTLEMENT OFFER.*—*The*
 24 *Secretary shall review any additional informa-*
 25 *tion furnished by the provider of services, physi-*

1 *cian, practitioner, or supplier under subpara-*
 2 *graph (B)(ii). Taking into consideration such*
 3 *information, the Secretary shall determine if*
 4 *there still appears to be an overpayment. If so,*
 5 *the Secretary—*

6 *“(i) shall provide notice of such deter-*
 7 *mination to the provider of services, physi-*
 8 *cian, practitioner, or supplier, including an*
 9 *explanation of the reason for such deter-*
 10 *mination; and*

11 *“(ii) in order to resolve the overpay-*
 12 *ment, may offer the provider of services,*
 13 *physician, practitioner, or supplier—*

14 *“(I) the opportunity for a statis-*
 15 *tically valid random sample; or*

16 *“(II) a consent settlement.*

17 *The opportunity provided under clause (ii)(I)*
 18 *does not waive any appeal rights with respect to*
 19 *the alleged overpayment involved.*

20 *“(D) CONSENT SETTLEMENT DEFINED.—*

21 *For purposes of this paragraph, the term ‘con-*
 22 *sent settlement’ means an agreement between the*
 23 *Secretary and a provider of services, physician,*
 24 *practitioner, or supplier whereby both parties*
 25 *agree to settle a projected overpayment based on*

1 *less than a statistically valid sample of claims*
 2 *and the provider of services, physician, practi-*
 3 *tioner, or supplier agrees not to appeal the*
 4 *claims involved.”.*

5 ***(b) EFFECTIVE DATES AND DEADLINES.—***

6 *(1) Not later than 1 year after the date of enact-*
 7 *ment of this Act, the Secretary shall first—*

8 *(A) develop standards for the recovery of*
 9 *overpayments under section 1874A(h)(1)(B) of*
 10 *the Social Security Act, as added by subsection*
 11 *(a);*

12 *(B) establish the process for notice of over-*
 13 *utilization of billing codes under section*
 14 *1874A(h)(4) of the Social Security Act, as added*
 15 *by subsection (a); and*

16 *(C) establish a standard methodology for se-*
 17 *lection of sample claims for abnormal billing*
 18 *patterns under section 1874A(h)(5) of the Social*
 19 *Security Act, as added by subsection (a).*

20 *(2) Section 1874A(h)(2) of the Social Security*
 21 *Act, as added by subsection (a), shall apply to actions*
 22 *taken after the date that is 1 year after the date of*
 23 *enactment of this Act.*

1 (3) *Section 1874A(h)(3) of the Social Security*
 2 *Act, as added by subsection (a), shall apply to audits*
 3 *initiated after the date of enactment of this Act.*

4 (4) *Section 1874A(h)(6) of the Social Security*
 5 *Act, as added by subsection (a), shall apply to consent*
 6 *settlements entered into after the date of enactment of*
 7 *this Act.*

8 **SEC. 543. PROCESS FOR CORRECTION OF MINOR ERRORS**
 9 **AND OMISSIONS ON CLAIMS WITHOUT PUR-**
 10 **SUING APPEALS PROCESS.**

11 (a) *IN GENERAL.*—*The Secretary shall develop, in con-*
 12 *sultation with appropriate medicare contractors (as defined*
 13 *in section 1889(e) of the Social Security Act, as added by*
 14 *section 531(d)(1)) and representatives of providers of serv-*
 15 *ices, physicians, practitioners, facilities, and suppliers, a*
 16 *process whereby, in the case of minor errors or omissions*
 17 *(as defined by the Secretary) that are detected in the sub-*
 18 *mission of claims under the programs under title XVIII of*
 19 *such Act, a provider of services, physician, practitioner, fa-*
 20 *cility, or supplier is given an opportunity to correct such*
 21 *an error or omission without the need to initiate an appeal.*
 22 *Such process shall include the ability to resubmit corrected*
 23 *claims.*

1 (b) *DEADLINE.*—Not later than 1 year after the date
 2 of enactment of this Act, the Secretary shall first develop
 3 the process under subsection (a).

4 **SEC. 544. AUTHORITY TO WAIVE A PROGRAM EXCLUSION.**

5 The first sentence of section 1128(c)(3)(B) (42 U.S.C.
 6 1320a–7(c)(3)(B)) is amended to read as follows: “Subject
 7 to subparagraph (G), in the case of an exclusion under sub-
 8 section (a), the minimum period of exclusion shall be not
 9 less than 5 years, except that, upon the request of an admin-
 10 istrator of a Federal health care program (as defined in
 11 section 1128B(f)) who determines that the exclusion would
 12 impose a hardship on beneficiaries of that program, the Sec-
 13 retary may, after consulting with the Inspector General of
 14 the Department of Health and Human Services, waive the
 15 exclusion under subsection (a)(1), (a)(3), or (a)(4) with re-
 16 spect to that program in the case of an individual or entity
 17 that is the sole community physician or sole source of essen-
 18 tial specialized services in a community.”.

19 **Subtitle F—Other Improvements**

20 **SEC. 551. INCLUSION OF ADDITIONAL INFORMATION IN NO-**
 21 **TICES TO BENEFICIARIES ABOUT SKILLED**
 22 **NURSING FACILITY AND HOSPITAL BENEFITS.**

23 (a) *IN GENERAL.*—The Secretary shall provide that in
 24 medicare beneficiary notices provided (under section
 25 1806(a) of the Social Security Act, 42 U.S.C. 1395b–7(a))

1 *with respect to the provision of post-hospital extended care*
 2 *services and inpatient hospital services under part A of title*
 3 *XVIII of the Social Security Act, there shall be included*
 4 *information on the number of days of coverage of such serv-*
 5 *ices remaining under such part for the medicare beneficiary*
 6 *and spell of illness involved.*

7 (b) *EFFECTIVE DATE.*—*Subsection (a) shall apply to*
 8 *notices provided during calendar quarters beginning more*
 9 *than 6 months after the date of enactment of this Act.*

10 **SEC. 552. INFORMATION ON MEDICARE-CERTIFIED SKILLED**
 11 **NURSING FACILITIES IN HOSPITAL DIS-**
 12 **CHARGE PLANS.**

13 (a) *AVAILABILITY OF DATA.*—*The Secretary shall pub-*
 14 *licly provide information that enables hospital discharge*
 15 *planners, medicare beneficiaries, and the public to identify*
 16 *skilled nursing facilities that are participating in the medi-*
 17 *care program.*

18 (b) *INCLUSION OF INFORMATION IN CERTAIN HOS-*
 19 *PITAL DISCHARGE PLANS.*—

20 (1) *IN GENERAL.*—*Section 1861(ee)(2)(D) (42*
 21 *U.S.C. 1395x(ee)(2)(D)) is amended—*

22 (A) *by striking “hospice services” and in-*
 23 *serting “hospice care and post-hospital extended*
 24 *care services”; and*

1 (B) by inserting before the period at the end
 2 the following: “and, in the case of individuals
 3 who are likely to need post-hospital extended care
 4 services, the availability of such services through
 5 facilities that participate in the program under
 6 this title and that serve the area in which the
 7 patient resides”.

8 (2) *EFFECTIVE DATE.*—The amendments made
 9 by paragraph (1) shall apply to discharge plans made
 10 on or after such date as the Secretary shall specify,
 11 but not later than 6 months after the date the Sec-
 12 retary provides for availability of information under
 13 subsection (a).

14 **SEC. 553. EVALUATION AND MANAGEMENT DOCUMENTA-**
 15 **TION GUIDELINES CONSIDERATION.**

16 The Secretary shall ensure, before making changes in
 17 documentation guidelines for, or clinical examples of, or
 18 codes to report evaluation and management physician serv-
 19 ices under title XVIII of Social Security Act, that the proc-
 20 ess used in developing such guidelines, examples, or codes
 21 was widely consultative among physicians, reflects a broad
 22 consensus among specialties, and would allow verification
 23 of reported and furnished services.

1 **SEC. 554. COUNCIL FOR TECHNOLOGY AND INNOVATION.**

2 *Section 1868 (42 U.S.C. 1395ee), as amended by sec-*
 3 *tion 534(a), is amended by adding at the end the following*
 4 *new subsection:*

5 “(c) **COUNCIL FOR TECHNOLOGY AND INNOVATION.**—

6 “(1) **ESTABLISHMENT.**—*The Secretary shall es-*
 7 *tablish a Council for Technology and Innovation*
 8 *within the Centers for Medicare & Medicaid Services*
 9 *(in this section referred to as ‘CMS’).*

10 “(2) **COMPOSITION.**—*The Council shall be com-*
 11 *posed of senior CMS staff and clinicians and shall be*
 12 *chaired by the Executive Coordinator for Technology*
 13 *and Innovation (appointed or designated under para-*
 14 *graph (4)).*

15 “(3) **DUTIES.**—*The Council shall coordinate the*
 16 *activities of coverage, coding, and payment processes*
 17 *under this title with respect to new technologies and*
 18 *procedures, including new drug therapies, and shall*
 19 *coordinate the exchange of information on new tech-*
 20 *nologies between CMS and other entities that make*
 21 *similar decisions.*

22 “(4) **EXECUTIVE COORDINATOR FOR TECH-**
 23 **NOLOGY AND INNOVATION.**—*The Secretary shall ap-*
 24 *point (or designate) a noncareer appointee (as defined*
 25 *in section 3132(a)(7) of title 5, United States Code)*
 26 *who shall serve as the Executive Coordinator for Tech-*

1 *nology and Innovation. Such executive coordinator*
 2 *shall report to the Administrator of CMS, shall chair*
 3 *the Council, shall oversee the execution of its duties,*
 4 *and shall serve as a single point of contact for outside*
 5 *groups and entities regarding the coverage, coding,*
 6 *and payment processes under this title.”.*

7 **SEC. 555. TREATMENT OF CERTAIN DENTAL CLAIMS.**

8 *(a) IN GENERAL.—Section 1862 (42 U.S.C. 1395y) is*
 9 *amended by adding after subsection (g) the following new*
 10 *subsection:*

11 *“(h)(1) Subject to paragraph (2), a group health plan*
 12 *(as defined in subsection (a)(1)(A)(v)) providing supple-*
 13 *mental or secondary coverage to individuals also entitled*
 14 *to services under this title shall not require a medicare*
 15 *claims determination under this title for dental benefits spe-*
 16 *cifically excluded under subsection (a)(12) as a condition*
 17 *of making a claims determination for such benefits under*
 18 *the group health plan.*

19 *“(2) A group health plan may require a claims deter-*
 20 *mination under this title in cases involving or appearing*
 21 *to involve inpatient dental hospital services or dental serv-*
 22 *ices expressly covered under this title pursuant to actions*
 23 *taken by the Secretary.”.*

1 (b) *EFFECTIVE DATE.*—*The amendment made by sub-*
 2 *section (a) shall take effect on the date that is 60 days after*
 3 *the date of enactment of this Act.*

4 ***TITLE VI—OTHER PROVISIONS***

5 ***SEC. 601. INCREASE IN MEDICAID DSH ALLOTMENTS FOR*** 6 ***FISCAL YEARS 2004 AND 2005.***

7 (a) *IN GENERAL.*—*Section 1923(f)(4) (42 U.S.C.*
 8 *1396r-4(f)(4)) is amended—*

9 (1) *in the paragraph heading, by striking “FIS-*
 10 *CAL YEARS 2001 AND 2002” and inserting “CERTAIN*
 11 *FISCAL YEARS”;*

12 (2) *in subparagraph (A)—*

13 (A) *in clause (i)—*

14 (i) *by striking “paragraph (2)” and*
 15 *inserting “paragraphs (2) and (3)”;* and

16 (ii) *by striking “and” at the end;*

17 (B) *in clause (ii), by striking the period*
 18 *and inserting a semicolon; and*

19 (C) *by adding at the end the following:*

20 “(iii) *for fiscal year 2004, shall be the*
 21 *DSH allotment determined under para-*
 22 *graph (3) for that fiscal year increased by*
 23 *the amount equal to the product of 0.50 and*
 24 *the difference between—*

1 “(I) the amount that the DSH al-
 2 lotment would be if the DSH allotment
 3 for the State determined under clause
 4 (ii) were increased, subject to subpara-
 5 graph (B) and paragraph (5), by the
 6 percentage change in the Consumer
 7 Price Index for all urban consumers
 8 (all items; U.S. city average) for each
 9 of fiscal years 2002 and 2003; and

10 “(II) the DSH allotment deter-
 11 mined under paragraph (3) for the
 12 State for fiscal year 2004; and

13 “(iv) for fiscal year 2005, shall be the
 14 DSH allotment determined under para-
 15 graph (3) for that fiscal year increased by
 16 the amount equal to the product of 0.50 and
 17 the difference between—

18 “(I) the amount that the DSH al-
 19 lotment would be if the DSH allotment
 20 for the State determined under clause
 21 (ii) were increased, subject to subpara-
 22 graph (B) and paragraph (5), by the
 23 percentage change in the Consumer
 24 Price Index for all urban consumers
 25 (all items; U.S. city average) for each

1 of fiscal years 2002, 2003, and 2004;
2 and

3 “(II) the DSH allotment deter-
4 mined under paragraph (3) for the
5 State for fiscal year 2005.”; and

6 (3) in subparagraph (C)—

7 (A) in the subparagraph heading, by strik-
8 ing “AFTER FISCAL YEAR 2002” and inserting
9 “FOR OTHER FISCAL YEARS”; and

10 (B) by striking “2003 or” and inserting
11 “2003, fiscal year 2006, or”.

12 (b) DSH ALLOTMENT FOR THE DISTRICT OF COLUM-
13 BIA.—Section 1923(f)(4) (42 U.S.C. 1396r-4(f)(4)), as
14 amended by paragraph (1), is amended—

15 (1) in subparagraph (A), by inserting “and ex-
16 cept as provided in subparagraph (C)” after “para-
17 graph (2)”;

18 (2) by redesignating subparagraph (C) as sub-
19 paragraph (D); and

20 (3) by inserting after subparagraph (B) the fol-
21 lowing:

22 “(C) DSH ALLOTMENT FOR THE DISTRICT
23 OF COLUMBIA.—

24 “(i) IN GENERAL.—Notwithstanding
25 subparagraph (A), the DSH allotment for

1 *the District of Columbia for fiscal year*
 2 *2004, shall be determined by substituting*
 3 *“49” for “32” in the item in the table con-*
 4 *tained in paragraph (2) with respect to the*
 5 *DSH allotment for FY 00 (fiscal year 2000)*
 6 *for the District of Columbia, and then in-*
 7 *creasing such allotment, subject to subpara-*
 8 *graph (B) and paragraph (5), by the per-*
 9 *centage change in the Consumer Price Index*
 10 *for all urban consumers (all items; U.S.*
 11 *city average) for each of fiscal years 2000,*
 12 *2001, 2002, and 2003.*

13 “(ii) *NO APPLICATION TO ALLOTMENTS*
 14 *AFTER FISCAL YEAR 2004.—The DSH allot-*
 15 *ment for the District of Columbia for fiscal*
 16 *year 2003, fiscal year 2005, or any suc-*
 17 *ceeding fiscal year shall be determined*
 18 *under paragraph (3) without regard to the*
 19 *DSH allotment determined under clause*
 20 *(i).”.*

21 (c) *CONFORMING AMENDMENT.—Section 1923(f)(3) of*
 22 *such Act (42 U.S.C. 1396r-4(f)(3)) is amended by inserting*
 23 *“, paragraph (4),” after “subparagraph (B)”.*

24 (d) *URBAN HEALTH PROVIDER ADJUSTMENT.—*

1 (1) *IN GENERAL.*—Beginning with fiscal year
 2 2004, notwithstanding section 1923(f) of the Social
 3 Security Act (42 U.S.C. 1396r–4(f)) and subject to
 4 paragraph (3), with respect to a State, payment ad-
 5 justments made under title XIX of the Social Security
 6 Act (42 U.S.C. 1396 et seq.) to a hospital described
 7 in paragraph (2) shall be made without regard to the
 8 DSH allotment limitation for the State determined
 9 under section 1923(f) of that Act (42 U.S.C. 1396r–
 10 4(f)).

11 (2) *HOSPITAL DESCRIBED.*—A hospital is de-
 12 scribed in this paragraph if the hospital—

13 (A) is owned or operated by a State (as de-
 14 fined for purposes of title XIX of the Social Se-
 15 curity Act), or by an instrumentality or a mu-
 16 nicipal governmental unit within a State (as so
 17 defined) as of January 1, 2003; and

18 (B) is located in Marion County, Indiana.

19 (3) *LIMITATION.*—The payment adjustment de-
 20 scribed in paragraph (1) for fiscal year 2004 and
 21 each fiscal year thereafter shall not exceed 175 percent
 22 of the costs of furnishing hospital services described in
 23 section 1923(g)(1)(A) of the Social Security Act (42
 24 U.S.C. 1396r–4(g)(1)(A)).

1 **SEC. 602. INCREASE IN FLOOR FOR TREATMENT AS AN EX-**
 2 **TREMELY LOW DSH STATE UNDER THE MED-**
 3 **ICAID PROGRAM FOR FISCAL YEARS 2004 AND**
 4 **2005.**

5 (a) *IN GENERAL.*—Section 1923(f)(5) (42 U.S.C.
 6 1396r–4(f)(5)) is amended—

7 (1) by striking “In the case of” and inserting the
 8 following:

9 “(A) *IN GENERAL.*—In the case of”; and

10 (2) by adding at the end the following:

11 “(B) *INCREASE IN FLOOR FOR FISCAL*
 12 *YEARS 2004 AND 2005.*—

13 “(i) *FISCAL YEAR 2004.*—In the case of
 14 a State in which the total expenditures
 15 under the State plan (including Federal
 16 and State shares) for disproportionate share
 17 hospital adjustments under this section for
 18 fiscal year 2000, as reported to the Admin-
 19 istrator of the Centers for Medicare & Med-
 20 icaid Services as of August 31, 2003, is
 21 greater than 0 but less than 3 percent of the
 22 State’s total amount of expenditures under
 23 the State plan for medical assistance during
 24 the fiscal year, the DSH allotment for fiscal
 25 year 2004 shall be increased to 3 percent of
 26 the State’s total amount of expenditures

1 *under such plan for such assistance during*
2 *such fiscal year.*

3 “(ii) *FISCAL YEAR 2005.—In the case of*
4 *a State in which the total expenditures*
5 *under the State plan (including Federal*
6 *and State shares) for disproportionate share*
7 *hospital adjustments under this section for*
8 *fiscal year 2001, as reported to the Admin-*
9 *istrator of the Centers for Medicare & Med-*
10 *icaid Services as of August 31, 2004, is*
11 *greater than 0 but less than 3 percent of the*
12 *State’s total amount of expenditures under*
13 *the State plan for medical assistance during*
14 *the fiscal year, the DSH allotment for fiscal*
15 *year 2005 shall be the DSH allotment deter-*
16 *mined for the State for fiscal year 2004*
17 *(under clause (i) or paragraph (4) (as ap-*
18 *plicable)), increased by the percentage*
19 *change in the consumer price index for all*
20 *urban consumers (all items; U.S. city aver-*
21 *age) for fiscal year 2004.*

22 “(iii) *NO APPLICATION TO ALLOT-*
23 *MENTS AFTER FISCAL YEAR 2005.—The*
24 *DSH allotment for any State for fiscal year*
25 *2006 or any succeeding fiscal year shall be*

1 *determined under this subsection without*
 2 *regard to the DSH allotments determined*
 3 *under this subparagraph.”.*

4 ***(b) ALLOTMENT ADJUSTMENT.—***

5 ***(1) IN GENERAL.—****Section 1923(f) of the Social*
 6 *Security Act (42 U.S.C. 1396r–4(f)) is amended—*

7 ***(A)*** *by redesignating paragraph (6) as*
 8 *paragraph (7); and*

9 ***(B)*** *by inserting after paragraph (5) the fol-*
 10 *lowing:*

11 ***“(6) ALLOTMENT ADJUSTMENT.—****Only with re-*
 12 *spect to fiscal year 2004 or 2005, if a statewide waiv-*
 13 *er under section 1115 that was implemented on Janu-*
 14 *ary 1, 1994, is revoked or terminated before the end*
 15 *of either such fiscal year, the Secretary shall—*

16 ***“(A)*** *permit the State whose waiver was re-*
 17 *voked or terminated to submit an amendment to*
 18 *its State plan that would describe the method-*
 19 *ology to be used by the State (after the effective*
 20 *date of such revocation or termination) to iden-*
 21 *tify and make payments to disproportionate*
 22 *share hospitals, including children’s hospitals*
 23 *and institutions for mental diseases or other*
 24 *mental health facilities (other than State-owned*
 25 *institutions or facilities), on the basis of the pro-*

1 *portion of patients served by such hospitals that*
 2 *are low-income patients with special needs; and*

3 *“(B) provide for purposes of this subsection*
 4 *for computation of an appropriate DSH allot-*
 5 *ment for the State for fiscal year 2004 or 2005*
 6 *(or both) that provides for the maximum amount*
 7 *(permitted consistent with paragraph (3)(B)(ii))*
 8 *that does not result in greater expenditures*
 9 *under this title than would have been made if*
 10 *such waiver had not been revoked or termi-*
 11 *nated.”.*

12 *(2) TREATMENT OF INSTITUTIONS FOR MENTAL*
 13 *DISEASES.—Section 1923(h)(1) of the Social Security*
 14 *Act (42 U.S.C. 1396r-4(h)(1)) is amended—*

15 *(A) in paragraph (1), in the matter pre-*
 16 *ceding subparagraph (A), by inserting “(subject*
 17 *to paragraph (3))” after “the lesser of the fol-*
 18 *lowing”; and*

19 *(B) by adding at the end the following new*
 20 *paragraph:*

21 *“(3) SPECIAL RULE.—The limitation of para-*
 22 *graph (1) shall not apply in the case of a State to*
 23 *which subsection (f)(6) applies.”.*

1 (3) *APPLICATION TO HAWAII.*—Section 1923(f)
 2 (42 U.S.C. 1396r-4(f)), as amended by paragraph
 3 (1), is amended—

4 (A) by redesignating paragraph (7) as
 5 paragraph (8); and

6 (B) by inserting after paragraph (6), the
 7 following:

8 “(7) *TREATMENT OF HAWAII AS A LOW-DSH*
 9 *STATE.*—The Secretary shall compute a DSH allot-
 10 ment for the State of Hawaii for each of fiscal years
 11 2004 and 2005 in the same manner as DSH allot-
 12 ments are determined with respect to those States to
 13 which paragraph (5) applies (but without regard to
 14 the requirement under such paragraph that total ex-
 15 penditures under the State plan for disproportionate
 16 share hospital adjustments for any fiscal year exceeds
 17 0).”.

18 **SEC. 603. INCREASED REPORTING REQUIREMENTS TO EN-**
 19 **SURE THE APPROPRIATENESS OF PAYMENT**
 20 **ADJUSTMENTS TO DISPROPORTIONATE**
 21 **SHARE HOSPITALS UNDER THE MEDICAID**
 22 **PROGRAM.**

23 Section 1923 (42 U.S.C. 1396r-4) is amended by add-
 24 ing at the end the following new subsection:

1 “(j) *ANNUAL REPORTS REGARDING PAYMENT ADJUST-*
 2 *MENTS.*—*With respect to fiscal year 2004 and each fiscal*
 3 *year thereafter, the Secretary shall require a State, as a*
 4 *condition of receiving a payment under section 1903(a)(1)*
 5 *with respect to a payment adjustment made under this sec-*
 6 *tion, to submit an annual report that—*

7 “(1) *identifies each disproportionate share hos-*
 8 *pital that received a payment adjustment under this*
 9 *section for the preceding fiscal year and the amount*
 10 *of the payment adjustment made to such hospital for*
 11 *the preceding fiscal year; and*

12 “(2) *includes such other information as the Sec-*
 13 *retary determines necessary to ensure the appro-*
 14 *priateness of the payment adjustments made under*
 15 *this section for the preceding fiscal year.”.*

16 **SEC. 604. CLARIFICATION OF INCLUSION OF INPATIENT**
 17 **DRUG PRICES CHARGED TO CERTAIN PUBLIC**
 18 **HOSPITALS IN THE BEST PRICE EXEMPTIONS**
 19 **FOR THE MEDICAID DRUG REBATE PROGRAM.**

20 (a) *IN GENERAL.*—*Section 1927(c)(1)(C)(i)(I) of the*
 21 *Social Security Act (42 U.S.C. 1396r–8(c)(1)(C)(i)(I)) is*
 22 *amended by inserting before the semicolon the following:*
 23 *“(including inpatient prices charged to hospitals described*
 24 *in section 340B(a)(4)(L) of the Public Health Service Act)”.*

1 (b) *ANTI-DIVERSION PROTECTION.—Section*
 2 1927(c)(1)(C) of the Social Security Act (42 U.S.C. 1396r–
 3 8(c)(1)(C)) is amended by adding at the end the following:

4 “(iii) *APPLICATION OF AUDITING AND*
 5 *RECORDKEEPING REQUIREMENTS.—With re-*
 6 *spect to a covered entity described in section*
 7 *340B(a)(4)(L) of the Public Health Service*
 8 *Act, any drug purchased for inpatient use*
 9 *shall be subject to the auditing and record-*
 10 *keeping requirements described in section*
 11 *340B(a)(5)(C) of the Public Health Service*
 12 *Act.”.*

13 (c) *EFFECTIVE DATE.—The amendments made by this*
 14 *section take effect on October 1, 2003.*

15 **SEC. 605. ASSISTANCE WITH COVERAGE OF LEGAL IMMI-**
 16 **GRANTS UNDER THE MEDICAID PROGRAM**
 17 **AND SCHIP.**

18 (a) *MEDICAID PROGRAM.—Section 1903(v) (42 U.S.C.*
 19 *1396b(v)) is amended—*

20 (1) *in paragraph (1), by striking “paragraph*
 21 *(2)” and inserting “paragraphs (2) and (4)”;* and

22 (2) *by adding at the end the following new para-*
 23 *graph:*

24 “(4)(A) *With respect to any or all of fiscal years 2005*
 25 *through 2007, a State may elect (in a plan amendment*

1 *under this title) to provide medical assistance under this*
 2 *title (including under a waiver authorized by the Secretary)*
 3 *for aliens who are lawfully residing in the United States*
 4 *(including battered aliens described in section 431(c) of*
 5 *such Act) and who are otherwise eligible for such assistance,*
 6 *within either or both of the following eligibility categories:*

7 “(i) *PREGNANT WOMEN.*—Women during preg-
 8 nancy (and during the 60-day period beginning on
 9 the last day of the pregnancy).

10 “(ii) *CHILDREN.*—Children (as defined under
 11 such plan), including optional targeted low-income
 12 children described in section 1905(u)(2)(B).

13 “(B)(i) *In the case of a State that has elected to pro-*
 14 *vide medical assistance to a category of aliens under sub-*
 15 *paragraph (A), no debt shall accrue under an affidavit of*
 16 *support against any sponsor of such an alien on the basis*
 17 *of provision of assistance to such category and the cost of*
 18 *such assistance shall not be considered as an unreimbursed*
 19 *cost.*

20 “(ii) *The provisions of sections 401(a), 402(b), 403,*
 21 *and 421 of the Personal Responsibility and Work Oppor-*
 22 *tunity Reconciliation Act of 1996 shall not apply to a State*
 23 *that makes an election under subparagraph (A).”.*

24 (b) *SCHIP.*—Section 2107(e)(1) (42 U.S.C.
 25 1397gg(e)(1)) is amended by redesignating subparagraphs

1 (C) and (D) as subparagraph (D) and (E), respectively,
 2 and by inserting after subparagraph (B) the following new
 3 subparagraph:

4 “(C) Section 1903(v)(4) (relating to op-
 5 tional coverage of categories of permanent resi-
 6 dent alien children), but only if the State has
 7 elected to apply such section to the category of
 8 children under title XIX and only with respect
 9 to any or all of fiscal years 2005 through 2007.”.

10 **SEC. 606. ESTABLISHMENT OF CONSUMER OMBUDSMAN AC-**
 11 **COUNT.**

12 (a) *IN GENERAL*.—Section 1817 (42 U.S.C. 1395i) is
 13 amended by adding at the end the following new subsection:

14 “(i) *CONSUMER OMBUDSMAN ACCOUNT*.—

15 “(1) *ESTABLISHMENT*.—There is hereby estab-
 16 lished in the Trust Fund an expenditure account to
 17 be known as the ‘Consumer Ombudsman Account’ (in
 18 this subsection referred to as the ‘Account’).

19 “(2) *APPROPRIATED AMOUNTS TO ACCOUNT FOR*
 20 *HEALTH INSURANCE INFORMATION, COUNSELING, AND*
 21 *ASSISTANCE GRANTS*.—

22 “(A) *IN GENERAL*.—There are hereby ap-
 23 propriated to the Account from the Trust Fund
 24 for each fiscal year beginning with fiscal year
 25 2005, the amount described in subparagraph (B)

1 *for such fiscal year for the purpose of making*
 2 *grants under section 4360 of the Omnibus Budg-*
 3 *et Reconciliation Act of 1990.*

4 *“(B) AMOUNT DESCRIBED.—For purposes of*
 5 *subparagraph (A), the amount described in this*
 6 *subparagraph for a fiscal year is the amount*
 7 *equal to the product of—*

8 *“(i) \$1; and*

9 *“(ii) the total number of individuals*
 10 *receiving benefits under this title for the cal-*
 11 *endar year ending on December 31 of the*
 12 *preceding fiscal year.”.*

13 *(b) CONFORMING AMENDMENT.—Section 4360(g) of*
 14 *the Omnibus Budget Reconciliation Act of 1990 (42 U.S.C.*
 15 *1395b–4(g)) is amended to read as follows:*

16 *“(g) FUNDING.—The Secretary shall use amounts ap-*
 17 *propriated to the Consumer Ombudsman Account in ac-*
 18 *cordance with section 1817(i) of the Social Security Act for*
 19 *a fiscal year for making grants under this section for that*
 20 *fiscal year.”.*

21 **SEC. 607. GAO STUDY REGARDING IMPACT OF ASSETS TEST**
 22 **FOR LOW-INCOME BENEFICIARIES.**

23 *(a) STUDY.—The Comptroller General of the United*
 24 *States shall conduct a study to determine the extent to*
 25 *which drug utilization and access to covered drugs for an*

1 *individual described in subsection (b) differs from the drug*
 2 *utilization and access to covered drugs of an individual who*
 3 *qualifies for the transitional assistance prescription drug*
 4 *card program under section 1807A of the Social Security*
 5 *Act (as added by section 111) or for the premiums and cost-*
 6 *sharing subsidies applicable to a qualified medicare bene-*
 7 *ficiary, a specified low-income medicare beneficiary, or a*
 8 *qualifying individual under section 1860D–19 of the Social*
 9 *Security Act (as added by section 101).*

10 **(b) INDIVIDUAL DESCRIBED.**—*An individual is de-*
 11 *scribed in this subsection if the individual does not qualify*
 12 *for the transitional assistance prescription drug card pro-*
 13 *gram under section 1807A of the Social Security Act or*
 14 *for the premiums and cost-sharing subsidies applicable to*
 15 *a qualified medicare beneficiary, a specified low-income*
 16 *medicare beneficiary, or a qualifying individual under sec-*
 17 *tion 1860D–19 of the Social Security Act solely as a result*
 18 *of the application of an assets test to the individual.*

19 **(c) REPORT.**—*Not later than September 30, 2007, the*
 20 *Comptroller General shall submit a report to Congress on*
 21 *the study conducted under subsection (a) that includes such*
 22 *recommendations for legislation as the Comptroller General*
 23 *determines are appropriate.*

24 **(d) DEFINITIONS.**—*In this section:*

1 (1) *COVERED DRUGS.*—*The term “covered drugs”*
 2 *has the meaning given that term in section*
 3 *1860D(a)(D) of the Social Security Act.*

4 (2) *QUALIFIED MEDICARE BENEFICIARY; SPECI-*
 5 *FIED LOW-INCOME MEDICARE BENEFICIARY; QUALI-*
 6 *FYING INDIVIDUAL.*—*The terms “qualified medicare*
 7 *beneficiary”, “specified low-income medicare bene-*
 8 *ficiary” and “qualifying individual” have the mean-*
 9 *ing given those terms under section 1860D–19 of the*
 10 *Social Security Act.*

11 **SEC. 608. HEALTH CARE INFRASTRUCTURE IMPROVEMENT.**

12 *At the end of the Social Security Act, add the following*
 13 *new title:*

14 **“TITLE XXII—HEALTH CARE IN-**
 15 **FRASTRUCTURE IMPROVE-**
 16 **MENT**

17 **“SEC. 2201. DEFINITIONS.**

18 *“In this title, the following definitions apply:*

19 *“(1) ELIGIBLE PROJECT COSTS.—The term ‘eli-*
 20 *gible project costs’ means amounts substantially all of*
 21 *which are paid by, or for the account of, an obligor*
 22 *in connection with a project, including the cost of—*

23 *“(A) development phase activities, including*
 24 *planning, feasibility analysis, revenue fore-*
 25 *casting, environmental study and review, per-*

1 *mitting, architectural engineering and design*
 2 *work, and other preconstruction activities;*

3 *“(B) construction, reconstruction, rehabili-*
 4 *tation, replacement, and acquisition of facilities*
 5 *and real property (including land related to the*
 6 *project and improvements to land), environ-*
 7 *mental mitigation, construction contingencies,*
 8 *and acquisition of equipment;*

9 *“(C) capitalized interest necessary to meet*
 10 *market requirements, reasonably required reserve*
 11 *funds, capital issuance expenses, and other car-*
 12 *rying costs during construction;*

13 *“(D) major medical equipment determined*
 14 *to be appropriate by the Secretary; and*

15 *“(E) refinancing projects or activities that*
 16 *are otherwise eligible for financial assistance*
 17 *under subparagraphs (A) through (D).*

18 *“(2) FEDERAL CREDIT INSTRUMENT.—The term*
 19 *‘Federal credit instrument’ means a secured loan,*
 20 *loan guarantee, or line of credit authorized to be*
 21 *made available under this title with respect to a*
 22 *project.*

23 *“(3) INVESTMENT-GRADE RATING.—The term*
 24 *‘investment-grade rating’ means a rating category of*
 25 *BBB minus, Baa3, or higher assigned by a rating*

1 *agency to project obligations offered into the capital*
 2 *markets.*

3 “(4) *LENDER.*—*The term ‘lender’ means any*
 4 *non-Federal qualified institutional buyer (as defined*
 5 *in section 230.144A(a) of title 17, Code of Federal*
 6 *Regulations (or any successor regulation), known as*
 7 *Rule 144A(a) of the Securities and Exchange Com-*
 8 *mission and issued under the Securities Act of 1933*
 9 *(15 U.S.C. 77a et seq.), including—*

10 “(A) *a qualified retirement plan (as defined*
 11 *in section 4974(c) of the Internal Revenue Code*
 12 *of 1986) that is a qualified institutional buyer;*
 13 *and*

14 “(B) *a governmental plan (as defined in*
 15 *section 414(d) of the Internal Revenue Code of*
 16 *1986) that is a qualified institutional buyer.*

17 “(5) *LINE OF CREDIT.*—*The term ‘line of credit’*
 18 *means an agreement entered into by the Secretary*
 19 *with an obligor under section 2204 to provide a direct*
 20 *loan at a future date upon the occurrence of certain*
 21 *events.*

22 “(6) *LOAN GUARANTEE.*—*The term ‘loan guar-*
 23 *antee’ means any guarantee or other pledge by the*
 24 *Secretary to pay all or part of the principal of and*

1 *interest on a loan or other debt obligation issued by*
 2 *an obligor and funded by a lender.*

3 “(7) *LOCAL SERVICER.*—*The term ‘local servicer’*
 4 *means a State or local government or any agency of*
 5 *a State or local government that is responsible for*
 6 *servicing a Federal credit instrument on behalf of the*
 7 *Secretary.*

8 “(8) *OBLIGOR.*—*The term ‘obligor’ means a*
 9 *party primarily liable for payment of the principal*
 10 *of or interest on a Federal credit instrument, which*
 11 *party may be a corporation, partnership, joint ven-*
 12 *ture, trust, or governmental entity, agency, or instru-*
 13 *mentality.*

14 “(9) *PROJECT.*—*The term ‘project’ means any*
 15 *project that is designed to improve the health care in-*
 16 *frastructure, including the construction, renovation,*
 17 *or other capital improvement of any hospital, medical*
 18 *research facility, or other medical facility or the pur-*
 19 *chase of any equipment to be used in a hospital, re-*
 20 *search facility, or other medical research facility.*

21 “(10) *PROJECT OBLIGATION.*—*The term ‘project*
 22 *obligation’ means any note, bond, debenture, lease, in-*
 23 *stallment sale agreement, or other debt obligation*
 24 *issued or entered into by an obligor in connection*

1 *with the financing of a project, other than a Federal*
 2 *credit instrument.*

3 “(11) *RATING AGENCY.*—*The term ‘rating agen-*
 4 *cy’ means a bond rating agency identified by the Se-*
 5 *curities and Exchange Commission as a Nationally*
 6 *Recognized Statistical Rating Organization.*

7 “(12) *SECURED LOAN.*—*The term ‘secured loan’*
 8 *means a direct loan or other debt obligation issued by*
 9 *an obligor and funded by the Secretary in connection*
 10 *with the financing of a project under section 2203.*

11 “(13) *STATE.*—*The term ‘State’ has the meaning*
 12 *given the term in section 101 of title 23, United*
 13 *States Code.*

14 “(14) *SUBSIDY AMOUNT.*—*The term ‘subsidy*
 15 *amount’ means the amount of budget authority suffi-*
 16 *cient to cover the estimated long-term cost to the Fed-*
 17 *eral Government of a Federal credit instrument, cal-*
 18 *culated on a net present value basis, excluding ad-*
 19 *ministrative costs and any incidental effects on gov-*
 20 *ernmental receipts or outlays in accordance with the*
 21 *provisions of the Federal Credit Reform Act of 1990*
 22 *(2 U.S.C. 661 et seq.).*

23 “(15) *SUBSTANTIAL COMPLETION.*—*The term*
 24 *‘substantial completion’ means the opening of a*
 25 *project to patients or for research purposes.*

1 **“SEC. 2202. DETERMINATION OF ELIGIBILITY AND PROJECT**
 2 **SELECTION.**

3 “(a) *ELIGIBILITY.*—*To be eligible to receive financial*
 4 *assistance under this title, a project shall meet the following*
 5 *criteria:*

6 “(1) *APPLICATION.*—*A State, a local servicer*
 7 *identified under section 2205(a), or the entity under-*
 8 *taking a project shall submit a project application to*
 9 *the Secretary.*

10 “(2) *ELIGIBLE PROJECT COSTS.*—*To be eligible*
 11 *for assistance under this title, a project shall have*
 12 *total eligible project costs that are reasonably antici-*
 13 *pated to equal or exceed \$40,000,000.*

14 “(3) *SOURCES OF REPAYMENTS.*—*Project financ-*
 15 *ing shall be repayable, in whole or in part, from reli-*
 16 *able revenue sources as described in the application*
 17 *submitted under paragraph (1).*

18 “(4) *PUBLIC SPONSORSHIP OF PRIVATE ENTI-*
 19 *TIES.*—*In the case of a project that is undertaken by*
 20 *an entity that is not a State or local government or*
 21 *an agency or instrumentality of a State or local gov-*
 22 *ernment, the project that the entity is undertaking*
 23 *shall be publicly sponsored or sponsored by an entity*
 24 *that is described in section 501(c)(3) of the Internal*
 25 *Revenue Code of 1986 and exempt from tax under sec-*
 26 *tion 501(a) of such Code.*

1 “(b) *SELECTION AMONG ELIGIBLE PROJECTS.*—

2 “(1) *ESTABLISHMENT.*—*The Secretary shall es-*
 3 *tablish criteria for selecting among projects that meet*
 4 *the eligibility criteria specified in subsection (a).*

5 “(2) *SELECTION CRITERIA.*—

6 “(A) *IN GENERAL.*—*The selection criteria*
 7 *shall include the following:*

8 “(i) *The extent to which the project is*
 9 *nationally or regionally significant, in*
 10 *terms of expanding or improving the health*
 11 *care infrastructure of the United States or*
 12 *the region or in terms of the medical benefit*
 13 *that the project will have.*

14 “(ii) *The creditworthiness of the*
 15 *project, including a determination by the*
 16 *Secretary that any financing for the project*
 17 *has appropriate security features, such as a*
 18 *rate covenant, credit enhancement require-*
 19 *ments, or debt services coverages, to ensure*
 20 *repayment.*

21 “(iii) *The extent to which assistance*
 22 *under this title would foster innovative pub-*
 23 *lic-private partnerships and attract private*
 24 *debt or equity investment.*

1 “(iv) *The likelihood that assistance*
 2 *under this title would enable the project to*
 3 *proceed at an earlier date than the project*
 4 *would otherwise be able to proceed.*

5 “(v) *The extent to which the project*
 6 *uses or results in new technologies.*

7 “(vi) *The amount of budget authority*
 8 *required to fund the Federal credit instru-*
 9 *ment made available under this title.*

10 “(vii) *The extent to which the project*
 11 *helps maintain or protect the environment.*

12 “(B) *SPECIFIC REQUIREMENTS.—The selec-*
 13 *tion criteria shall require that a project*
 14 *applicant—*

15 “(i) *be engaged in research in the*
 16 *causes, prevention, and treatment of cancer;*

17 “(ii) *be designated as a cancer center*
 18 *for the National Cancer Institute or be des-*
 19 *ignated by the State as the official cancer*
 20 *institute of the State; and*

21 “(iii) *be located in a State that, on the*
 22 *date of enactment of this title, has a popu-*
 23 *lation of less than 3,000,000 individuals.*

24 “(C) *RATING LETTER.—For purposes of*
 25 *subparagraph (A)(ii), the Secretary shall require*

1 *each project applicant to provide a rating letter*
 2 *from at least 1 rating agency indicating that the*
 3 *project’s senior obligations have the potential to*
 4 *achieve an investment-grade rating with or with-*
 5 *out credit enhancement.*

6 **“SEC. 2203. SECURED LOANS.**

7 “(a) *IN GENERAL.*—

8 “(1) *AGREEMENTS.*—*Subject to paragraphs (2)*
 9 *through (4), the Secretary may enter into agreements*
 10 *with 1 or more obligors to make secured loans, the*
 11 *proceeds of which shall be used—*

12 “(A) *to finance eligible project costs;*

13 “(B) *to refinance interim construction fi-*
 14 *nancing of eligible project costs; or*

15 “(C) *to refinance existing debt or prior*
 16 *project obligations;*

17 *of any project selected under section 2202.*

18 “(2) *LIMITATION ON REFINANCING OF INTERIM*
 19 *CONSTRUCTION FINANCING.*—*A loan under paragraph*
 20 *(1) shall not refinance interim construction financing*
 21 *under paragraph (1)(B) later than 1 year after the*
 22 *date of substantial completion of the project.*

23 “(3) *RISK ASSESSMENT.*—*Before entering into*
 24 *an agreement for a secured loan under this subsection,*
 25 *the Secretary, in consultation with each rating agen-*

cy providing a rating letter under section 2202(b)(2)(B), shall determine an appropriate capital reserve subsidy amount for each secured loan, taking into account such letter.

“(4) INVESTMENT-GRADE RATING REQUIREMENT.—The funding of a secured loan under this section shall be contingent on the project’s senior obligations receiving an investment-grade rating, except that—

“(A) the Secretary may fund an amount of the secured loan not to exceed the capital reserve subsidy amount determined under paragraph (3) prior to the obligations receiving an investment-grade rating; and

“(B) the Secretary may fund the remaining portion of the secured loan only after the obligations have received an investment-grade rating by at least 1 rating agency.

“(b) TERMS AND LIMITATIONS.—

“(1) IN GENERAL.—A secured loan under this section with respect to a project shall be on such terms and conditions and contain such covenants, representations, warranties, and requirements (including requirements for audits) as the Secretary determines appropriate.

1 “(2) *MAXIMUM AMOUNT.*—*The amount of the se-*
 2 *cured loan shall not exceed 100 percent of the reason-*
 3 *ably anticipated eligible project costs.*

4 “(3) *PAYMENT.*—*The secured loan—*

5 “(A) *shall—*

6 “(i) *be payable, in whole or in part,*
 7 *from reliable revenue sources; and*

8 “(ii) *include a rate covenant, coverage*
 9 *requirement, or similar security feature*
 10 *supporting the project obligations; and*

11 “(B) *may have a lien on revenues described*
 12 *in subparagraph (A) subject to any lien securing*
 13 *project obligations.*

14 “(4) *INTEREST RATE.*—*The interest rate on the*
 15 *secured loan shall be not less than the yield on mar-*
 16 *ketable United States Treasury securities of a similar*
 17 *maturity to the maturity of the secured loan on the*
 18 *date of execution of the loan agreement.*

19 “(5) *MATURITY DATE.*—*The final maturity date*
 20 *of the secured loan shall be not later than 30 years*
 21 *after the date of substantial completion of the project.*

22 “(6) *NONSUBORDINATION.*—*The secured loan*
 23 *shall not be subordinated to the claims of any holder*
 24 *of project obligations in the event of bankruptcy, in-*
 25 *solvency, or liquidation of the obligor.*

1 “(7) *FEES.*—*The Secretary may establish fees at*
 2 *a level sufficient to cover all or a portion of the costs*
 3 *to the Federal Government of making a secured loan*
 4 *under this section.*

5 “(c) *REPAYMENT.*—

6 “(1) *SCHEDULE.*—*The Secretary shall establish*
 7 *a repayment schedule for each secured loan under this*
 8 *section based on the projected cash flow from project*
 9 *revenues and other repayment sources.*

10 “(2) *COMMENCEMENT.*—*Scheduled loan repay-*
 11 *ments of principal or interest on a secured loan under*
 12 *this section shall commence not later than 5 years*
 13 *after the date of substantial completion of the project.*

14 “(3) *SOURCES OF REPAYMENT FUNDS.*—*The*
 15 *sources of funds for scheduled loan repayments under*
 16 *this section shall include any revenue generated by*
 17 *the project.*

18 “(4) *DEFERRED PAYMENTS.*—

19 “(A) *AUTHORIZATION.*—*If, at any time*
 20 *during the 10 years after the date of substantial*
 21 *completion of the project, the project is unable to*
 22 *generate sufficient revenues to pay the scheduled*
 23 *loan repayments of principal and interest on the*
 24 *secured loan, the Secretary may, subject to sub-*
 25 *paragraph (C), allow the obligor to add unpaid*

1 *principal and interest to the outstanding balance*
 2 *of the secured loan.*

3 “(B) *INTEREST.*—*Any payment deferred*
 4 *under subparagraph (A) shall—*

5 “(i) *continue to accrue interest in ac-*
 6 *cordance with subsection (b)(4) until fully*
 7 *repaid; and*

8 “(ii) *be scheduled to be amortized over*
 9 *the remaining term of the loan beginning*
 10 *not later than 10 years after the date of*
 11 *substantial completion of the project in ac-*
 12 *cordance with paragraph (1).*

13 “(C) *CRITERIA.*—

14 “(i) *IN GENERAL.*—*Any payment de-*
 15 *ferral under subparagraph (A) shall be con-*
 16 *tingent on the project meeting criteria es-*
 17 *tablished by the Secretary.*

18 “(ii) *REPAYMENT STANDARDS.*—*The*
 19 *criteria established under clause (i) shall*
 20 *include standards for reasonable assurance*
 21 *of repayment.*

22 “(5) *PREPAYMENT.*—

23 “(A) *USE OF EXCESS REVENUES.*—*Any ex-*
 24 *cess revenues that remain after satisfying sched-*
 25 *uled debt service requirements on the project obli-*

gations and secured loan and all deposit requirements under the terms of any trust agreement, bond resolution, reimbursement agreement, credit agreement, loan agreement, or similar agreement securing project obligations may be applied annually to prepay the secured loan without penalty.

“(B) *USE OF PROCEEDS OF REFINANCING.*—The secured loan may be prepaid at any time without penalty, regardless of whether such repayment is from the proceeds of refinancing from non-Federal funding sources.

“(6) *FORGIVENESS OF INDEBTEDNESS.*—The Secretary may forgive a loan secured under this title under terms and conditions that are analogous to the loan forgiveness provision for student loans under part D of title IV of the Higher Education Act of 1965 (20 U.S.C. 1087a et seq.), except that the Secretary shall condition such forgiveness on the establishment by the project of—

“(A) an outreach program for cancer prevention, early diagnosis, and treatment that provides services to a substantial majority of the residents of a State or region, including residents of rural areas;

1 “(B) an outreach program for cancer pre-
 2 vention, early diagnosis, and treatment that pro-
 3 vides services to multiple Indian tribes; and

4 “(C)(i) unique research resources (such as
 5 population databases); or

6 “(ii) an affiliation with an entity that has
 7 unique research resources.

8 “(d) SALE OF SECURED LOANS.—

9 “(1) IN GENERAL.—Subject to paragraph (2), as
 10 soon as practicable after substantial completion of a
 11 project and after notifying the obligor, the Secretary
 12 may sell to another entity or reoffer into the capital
 13 markets a secured loan for the project if the Secretary
 14 determines that the sale or reoffering can be made on
 15 favorable terms.

16 “(2) CONSENT OF OBLIGOR.—In making a sale
 17 or reoffering under paragraph (1), the Secretary may
 18 not change the original terms and conditions of the
 19 secured loan without the written consent of the obli-
 20 gor.

21 “(e) LOAN GUARANTEES.—

22 “(1) IN GENERAL.—The Secretary may provide
 23 a loan guarantee to a lender in lieu of making a se-
 24 cured loan if the Secretary determines that the budg-

1 *etary cost of the loan guarantee is substantially the*
 2 *same as that of a secured loan.*

3 “(2) *TERMS.*—*The terms of a guaranteed loan*
 4 *shall be consistent with the terms set forth in this sec-*
 5 *tion for a secured loan, except that the rate on the*
 6 *guaranteed loan and any prepayment features shall*
 7 *be negotiated between the obligor and the lender, with*
 8 *the consent of the Secretary.*

9 **“SEC. 2204. LINES OF CREDIT.**

10 “(a) *IN GENERAL.*—

11 “(1) *AGREEMENTS.*—*Subject to paragraphs (2)*
 12 *through (4), the Secretary may enter into agreements*
 13 *to make available lines of credit to 1 or more obligors*
 14 *in the form of direct loans to be made by the Sec-*
 15 *retary at future dates on the occurrence of certain*
 16 *events for any project selected under section 2202.*

17 “(2) *USE OF PROCEEDS.*—*The proceeds of a line*
 18 *of credit made available under this section shall be*
 19 *available to pay debt service on project obligations*
 20 *issued to finance eligible project costs, extraordinary*
 21 *repair and replacement costs, operation and mainte-*
 22 *nance expenses, and costs associated with unexpected*
 23 *Federal or State environmental restrictions.*

24 “(3) *RISK ASSESSMENT.*—*Before entering into*
 25 *an agreement for a secured loan under this subsection,*

1 *the Secretary, in consultation with each rating agen-*
 2 *cy providing a rating letter under section*
 3 *2202(b)(2)(B), shall determine an appropriate sub-*
 4 *sidy amount for each secured loan, taking into ac-*
 5 *count such letter.*

6 “(4) *INVESTMENT-GRADE RATING REQUIRE-*
 7 *MENT.—The funding of a line of credit under this sec-*
 8 *tion shall be contingent on the project’s senior obliga-*
 9 *tions receiving an investment-grade rating from at*
 10 *least 1 rating agency.*

11 “(b) *TERMS AND LIMITATIONS.—*

12 “(1) *IN GENERAL.—A line of credit under this*
 13 *section with respect to a project shall be on such terms*
 14 *and conditions and contain such covenants, represen-*
 15 *tations, warranties, and requirements (including re-*
 16 *quirements for audits) as the Secretary determines*
 17 *appropriate.*

18 “(2) *MAXIMUM AMOUNTS.—*

19 “(A) *TOTAL AMOUNT.—The total amount of*
 20 *the line of credit shall not exceed 33 percent of*
 21 *the reasonably anticipated eligible project costs.*

22 “(B) *1-YEAR DRAWS.—The amount drawn*
 23 *in any 1 year shall not exceed 20 percent of the*
 24 *total amount of the line of credit.*

1 “(3) *DRAWS.*—Any draw on the line of credit
 2 shall represent a direct loan and shall be made only
 3 if net revenues from the project (including capitalized
 4 interest, any debt service reserve fund, and any other
 5 available reserve) are insufficient to pay the costs
 6 specified in subsection (a)(2).

7 “(4) *INTEREST RATE.*—The interest rate on a di-
 8 rect loan resulting from a draw on the line of credit
 9 shall be not less than the yield on 30-year marketable
 10 United States Treasury securities as of the date on
 11 which the line of credit is obligated.

12 “(5) *SECURITY.*—The line of credit—

13 “(A) shall—

14 “(i) be payable, in whole or in part,
 15 from reliable revenue sources; and

16 “(ii) include a rate covenant, coverage
 17 requirement, or similar security feature
 18 supporting the project obligations; and

19 “(B) may have a lien on revenues described
 20 in subparagraph (A) subject to any lien securing
 21 project obligations.

22 “(6) *PERIOD OF AVAILABILITY.*—The line of
 23 credit shall be available during the period beginning
 24 on the date of substantial completion of the project
 25 and ending not later than 10 years after that date.

1 “(7) *RIGHTS OF THIRD-PARTY CREDITORS.*—

2 “(A) *AGAINST FEDERAL GOVERNMENT.*—A
3 *third-party creditor of the obligor shall not have*
4 *any right against the Federal Government with*
5 *respect to any draw on the line of credit.*

6 “(B) *ASSIGNMENT.*—An obligor may assign
7 *the line of credit to 1 or more lenders or to a*
8 *trustee on the lenders’ behalf.*

9 “(8) *NONSUBORDINATION.*—A direct loan under
10 *this section shall not be subordinated to the claims of*
11 *any holder of project obligations in the event of bank-*
12 *ruptcy, insolvency, or liquidation of the obligor.*

13 “(9) *FEEES.*—The Secretary may establish fees at
14 *a level sufficient to cover all or a portion of the costs*
15 *to the Federal Government of providing a line of cred-*
16 *it under this section.*

17 “(10) *RELATIONSHIP TO OTHER CREDIT INSTRU-*
18 *MENTS.*—A project that receives a line of credit under
19 *this section also shall not receive a secured loan or*
20 *loan guarantee under section 2203 of an amount that,*
21 *combined with the amount of the line of credit, ex-*
22 *ceeds 100 percent of eligible project costs.*

23 “(c) *REPAYMENT.*—

24 “(1) *TERMS AND CONDITIONS.*—The Secretary
25 *shall establish repayment terms and conditions for*

1 *each direct loan under this section based on the pro-*
 2 *jected cash flow from project revenues and other re-*
 3 *payment sources.*

4 “(2) *TIMING.*—*All scheduled repayments of prin-*
 5 *icipal or interest on a direct loan under this section*
 6 *shall commence not later than 5 years after the end*
 7 *of the period of availability specified in subsection*
 8 *(b)(6) and be fully repaid, with interest, by the date*
 9 *that is 25 years after the end of the period of avail-*
 10 *ability specified in subsection (b)(6).*

11 “(3) *SOURCES OF REPAYMENT FUNDS.*—*The*
 12 *sources of funds for scheduled loan repayments under*
 13 *this section shall include reliable revenue sources.*

14 **“SEC. 2205. PROJECT SERVICING.**

15 “(a) *REQUIREMENT.*—*The State in which a project*
 16 *that receives financial assistance under this title is located*
 17 *may identify a local servicer to assist the Secretary in serv-*
 18 *icing the Federal credit instrument made available under*
 19 *this title.*

20 “(b) *AGENCY; FEES.*—*If a State identifies a local*
 21 *servicer under subsection (a), the local servicer—*

22 “(1) *shall act as the agent for the Secretary; and*

23 “(2) *may receive a servicing fee, subject to ap-*
 24 *proval by the Secretary.*

1 “(c) *LIABILITY.*—A local servicer identified under sub-
 2 section (a) shall not be liable for the obligations of the obli-
 3 gor to the Secretary or any lender.

4 “(d) *ASSISTANCE FROM EXPERT FIRMS.*—The Sec-
 5 retary may retain the services of expert firms in the field
 6 of project finance to assist in the underwriting and serv-
 7 icing of Federal credit instruments.

8 **“SEC. 2206. STATE AND LOCAL PERMITS.**

9 “The provision of financial assistance under this title
 10 with respect to a project shall not—

11 “(1) relieve any recipient of the assistance of any
 12 obligation to obtain any required State or local per-
 13 mit or approval with respect to the project;

14 “(2) limit the right of any unit of State or local
 15 government to approve or regulate any rate of return
 16 on private equity invested in the project; or

17 “(3) otherwise supersede any State or local law
 18 (including any regulation) applicable to the construc-
 19 tion or operation of the project.

20 **“SEC. 2207. REGULATIONS.**

21 “The Secretary may issue such regulations as the Sec-
 22 retary determines appropriate to carry out this title.

23 **“SEC. 2208. FUNDING.**

24 “(a) *FUNDING.*—

1 “(1) *IN GENERAL.*—*There are authorized to be*
 2 *appropriated to carry out this title, \$49,000,000 to*
 3 *remain available during the period beginning on July*
 4 *1, 2004 and ending on September 30, 2008.*

5 “(2) *ADMINISTRATIVE COSTS.*—*From funds*
 6 *made available under paragraph (1), the Secretary*
 7 *may use, for the administration of this title, not more*
 8 *than \$2,000,000 for each of fiscal years 2004 through*
 9 *2008.*

10 “(b) *CONTRACT AUTHORITY.*—*Notwithstanding any*
 11 *other provision of law, approval by the Secretary of a Fed-*
 12 *eral credit instrument that uses funds made available under*
 13 *this title shall be deemed to be acceptance by the United*
 14 *States of a contractual obligation to fund the Federal credit*
 15 *instrument.*

16 “(c) *AVAILABILITY.*—*Amounts appropriated under*
 17 *this section shall be available for obligation on July 1, 2004.*

18 **“SEC. 2209. REPORT TO CONGRESS.**

19 *“Not later than 4 years after the date of enactment*
 20 *of this title, the Secretary shall submit to Congress a report*
 21 *summarizing the financial performance of the projects that*
 22 *are receiving, or have received, assistance under this title,*
 23 *including a recommendation as to whether the objectives of*
 24 *this title are best served—*

1 “(1) by continuing the program under the au-
2 thority of the Secretary;

3 “(2) by establishing a Government corporation
4 or Government-sponsored enterprise to administer the
5 program; or

6 “(3) by phasing out the program and relying on
7 the capital markets to fund the types of infrastructure
8 investments assisted by this title without Federal par-
9 ticipation.”.

10 **SEC. 609. CAPITAL INFRASTRUCTURE REVOLVING LOAN**
11 **PROGRAM.**

12 (a) *IN GENERAL.*—Part A of title XVI of the Public
13 Health Service Act (42 U.S.C. 300q et seq.) is amended by
14 adding at the end the following new section:

15 “CAPITAL INFRASTRUCTURE REVOLVING LOAN PROGRAM

16 “SEC. 1603. (a) *AUTHORITY TO MAKE AND GUAR-*
17 *ANTEE LOANS.*—

18 “(1) *AUTHORITY TO MAKE LOANS.*—The Sec-
19 retary may make loans from the fund established
20 under section 1602(d) to any rural entity for projects
21 for capital improvements, including—

22 “(A) the acquisition of land necessary for
23 the capital improvements;

24 “(B) the renovation or modernization of
25 any building;

1 “(C) *the acquisition or repair of fixed or*
 2 *major movable equipment; and*

3 “(D) *such other project expenses as the Sec-*
 4 *retary determines appropriate.*

5 “(2) *AUTHORITY TO GUARANTEE LOANS.—*

6 “(A) *IN GENERAL.—The Secretary may*
 7 *guarantee the payment of principal and interest*
 8 *for loans made to rural entities for projects for*
 9 *any capital improvement described in paragraph*
 10 *(1) to any non-Federal lender.*

11 “(B) *INTEREST SUBSIDIES.—In the case of*
 12 *a guarantee of any loan made to a rural entity*
 13 *under subparagraph (A), the Secretary may pay*
 14 *to the holder of such loan, for and on behalf of*
 15 *the project for which the loan was made,*
 16 *amounts sufficient to reduce (by not more than*
 17 *3 percent) the net effective interest rate otherwise*
 18 *payable on such loan.*

19 “(b) *AMOUNT OF LOAN.—The principal amount of a*
 20 *loan directly made or guaranteed under subsection (a) for*
 21 *a project for capital improvement may not exceed*
 22 *\$5,000,000.*

23 “(c) *FUNDING LIMITATIONS.—*

24 “(1) *GOVERNMENT CREDIT SUBSIDY EXPO-*
 25 *SURE.—The total of the Government credit subsidy*

1 *exposure under the Credit Reform Act of 1990 scoring*
 2 *protocol with respect to the loans outstanding at any*
 3 *time with respect to which guarantees have been*
 4 *issued, or which have been directly made, under sub-*
 5 *section (a) may not exceed \$50,000,000 per year.*

6 “(2) *TOTAL AMOUNTS.*—Subject to paragraph
 7 (1), the total of the principal amount of all loans di-
 8 rectly made or guaranteed under subsection (a) may
 9 not exceed \$250,000,000 per year.

10 “(d) *CAPITAL ASSESSMENT AND PLANNING GRANTS.*—

11 “(1) *NONREPAYABLE GRANTS.*—Subject to para-
 12 graph (2), the Secretary may make a grant to a rural
 13 entity, in an amount not to exceed \$50,000, for pur-
 14 poses of capital assessment and business planning.

15 “(2) *LIMITATION.*—The cumulative total of
 16 grants awarded under this subsection may not exceed
 17 \$2,500,000 per year.

18 “(e) *TERMINATION OF AUTHORITY.*—The Secretary
 19 may not directly make or guarantee any loan under sub-
 20 section (a) or make a grant under subsection (d) after Sep-
 21 tember 30, 2008.”.

22 (b) *RURAL ENTITY DEFINED.*—Section 1624 of the
 23 Public Health Service Act (42 U.S.C. 300s–3) is amended
 24 by adding at the end the following new paragraph:

25 “(14)(A) The term ‘rural entity’ includes—

1 “(i) a rural health clinic, as defined in sec-
2 tion 1861(aa)(2) of the Social Security Act;

3 “(ii) any medical facility with at least 1
4 bed, but with less than 50 beds, that is located
5 in—

6 “(I) a county that is not part of a met-
7 ropolitan statistical area; or

8 “(II) a rural census tract of a metro-
9 politan statistical area (as determined
10 under the most recent modification of the
11 Goldsmith Modification, originally pub-
12 lished in the Federal Register on February
13 27, 1992 (57 Fed. Reg. 6725));

14 “(iii) a hospital that is classified as a
15 rural, regional, or national referral center under
16 section 1886(d)(5)(C) of the Social Security Act;
17 and

18 “(iv) a hospital that is a sole community
19 hospital (as defined in section 1886(d)(5)(D)(iii)
20 of the Social Security Act).

21 “(B) For purposes of subparagraph (A), the fact
22 that a clinic, facility, or hospital has been geographi-
23 cally reclassified under the medicare program under
24 title XVIII of the Social Security Act shall not pre-

1 *clude a hospital from being considered a rural entity*
 2 *under clause (i) or (ii) of subparagraph (A).”.*

3 *(c) CONFORMING AMENDMENTS.—Section 1602 of the*
 4 *Public Health Service Act (42 U.S.C. 300q–2) is*
 5 *amended—*

6 *(1) in subsection (b)(2)(D), by inserting “or*
 7 *1603(a)(2)(B)” after “1601(a)(2)(B)”;* and

8 *(2) in subsection (d)—*

9 *(A) in paragraph (1)(C), by striking “sec-*
 10 *tion 1601(a)(2)(B)” and inserting “sections*
 11 *1601(a)(2)(B) and 1603(a)(2)(B)”;* and

12 *(B) in paragraph (2)(A), by inserting “or*
 13 *1603(a)(2)(B)” after “1601(a)(2)(B)”.*

14 **SEC. 610. FEDERAL REIMBURSEMENT OF EMERGENCY**
 15 **HEALTH SERVICES FURNISHED TO UNDOCU-**
 16 **MENTED ALIENS.**

17 *(a) TOTAL AMOUNT AVAILABLE FOR ALLOTMENT.—*
 18 *There is appropriated, out of any funds in the Treasury*
 19 *not otherwise appropriated, \$250,000,000 for each of fiscal*
 20 *years 2005 through 2008, for the purpose of making allot-*
 21 *ments under this section to States described in paragraph*
 22 *(1) or (2) of subsection (b). Funds appropriated under the*
 23 *preceding sentence shall remain available until expended.*

24 *(b) STATE ALLOTMENTS.—*

1 (1) *BASED ON PERCENTAGE OF UNDOCUMENTED*
 2 *ALIENS.—*

3 (A) *IN GENERAL.—*Out of the amount ap-
 4 propriated under subsection (a) for a fiscal year,
 5 the Secretary shall use \$167,000,000 of such
 6 amount to make allotments for such fiscal year
 7 in accordance with subparagraph (B).

8 (B) *FORMULA.—*The amount of the allot-
 9 ment for each State for a fiscal year shall be
 10 equal to the product of—

11 (i) the total amount available for allot-
 12 ments under this paragraph for the fiscal
 13 year; and

14 (ii) the percentage of undocumented
 15 aliens residing in the State with respect to
 16 the total number of such aliens residing in
 17 all States, as determined by the Statistics
 18 Division of the Immigration and Natu-
 19 ralization Service, as of January 2003,
 20 based on the 2000 decennial census.

21 (2) *BASED ON NUMBER OF UNDOCUMENTED*
 22 *ALIEN APPREHENSION STATES.—*

23 (A) *IN GENERAL.—*Out of the amount ap-
 24 propriated under subsection (a) for a fiscal year,
 25 the Secretary shall use \$83,000,000 of such

1 *amount to make allotments for such fiscal year*
2 *for each of the 6 States with the highest number*
3 *of undocumented alien apprehensions for such*
4 *fiscal year.*

5 *(B) DETERMINATION OF ALLOTMENTS.—The*
6 *amount of the allotment for each State described*
7 *in subparagraph (A) for a fiscal year shall bear*
8 *the same ratio to the total amount available for*
9 *allotments under this paragraph for the fiscal*
10 *year as the ratio of the number of undocumented*
11 *alien apprehensions in the State in that fiscal*
12 *year bears to the total of such numbers for all*
13 *such States for such fiscal year.*

14 *(C) DATA.—For purposes of this paragraph,*
15 *the highest number of undocumented alien ap-*
16 *prehensions for a fiscal year shall be based on*
17 *the 4 most recent quarterly apprehension rates*
18 *for undocumented aliens in such States, as re-*
19 *ported by the Immigration and Naturalization*
20 *Service.*

21 *(3) RULE OF CONSTRUCTION.—Nothing in this*
22 *section shall be construed as prohibiting a State that*
23 *is described in both of paragraphs (1) and (2) from*
24 *receiving an allotment under both paragraphs for a*
25 *fiscal year.*

1 (c) *USE OF FUNDS.*—

2 (1) *AUTHORITY TO MAKE PAYMENTS.*—*From the*
3 *allotments made for a State under subsection (b) for*
4 *a fiscal year, the Secretary shall pay directly to local*
5 *governments, hospitals, or other providers located in*
6 *the State (including providers of services received*
7 *through an Indian Health Service facility whether*
8 *operated by the Indian Health Service or by an In-*
9 *Indian tribe or tribal organization) that provide un-*
10 *compensated emergency health services furnished to*
11 *undocumented aliens during that fiscal year, and to*
12 *the State, such amounts (subject to the total amount*
13 *available from such allotments) as the local govern-*
14 *ments, hospitals, providers, or State demonstrate were*
15 *incurred for the provision of such services during that*
16 *fiscal year.*

17 (2) *LIMITATION ON STATE USE OF FUNDS.*—
18 *Funds paid to a State from allotments made under*
19 *subsection (b) for a fiscal year may only be used for*
20 *making payments to local governments, hospitals, or*
21 *other providers for costs incurred in providing emer-*
22 *gency health services to undocumented aliens or for*
23 *State costs incurred with respect to the provision of*
24 *emergency health services to such aliens.*

1 (3) *INCLUSION OF COSTS INCURRED WITH RE-*
 2 *SPECT TO CERTAIN ALIENS.*—*Uncompensated emer-*
 3 *gency health services furnished to aliens who have*
 4 *been allowed to enter the United States for the sole*
 5 *purpose of receiving emergency health services may be*
 6 *included in the determination of costs incurred by a*
 7 *State, local government, hospital, or other provider*
 8 *with respect to the provision of such services.*

9 (d) *APPLICATIONS; ADVANCE PAYMENTS.*—

10 (1) *DEADLINE FOR ESTABLISHMENT OF APPLICA-*
 11 *TION PROCESS.*—24 (A) *IN GENERAL.*—*Not later*
 12 *than September 1, 2004, the Secretary shall establish*
 13 *a process under which States, local governments, hos-*
 14 *pitals, or other providers located in the State may*
 15 *apply for payments from allotments made under sub-*
 16 *section (b) for a fiscal year for uncompensated emer-*
 17 *gency health services furnished to undocumented*
 18 *aliens during that fiscal year.*

19 (B) *INCLUSION OF MEASURES TO COMBAT*
 20 *FRAUD.*—*The Secretary shall include in the*
 21 *process established under subparagraph (A)*
 22 *measures to ensure that fraudulent payments are*
 23 *not made from the allotments determined under*
 24 *subsection (b).*

1 (2) *ADVANCE PAYMENT; RETROSPECTIVE ADJUST-*
 2 *MENT.*—*The process established under paragraph (1)*
 3 *shall allow for making payments under this section*
 4 *for each quarter of a fiscal year on the basis of ad-*
 5 *vance estimates of expenditures submitted by appli-*
 6 *cants for such payments and such other investigation*
 7 *as the Secretary may find necessary, and for making*
 8 *reductions or increases in the payments as necessary*
 9 *to adjust for any overpayment or underpayment for*
 10 *prior quarters of such fiscal year.*

11 (e) *DEFINITIONS.*—*In this section:*

12 (1) *HOSPITAL.*—*The term “hospital” has the*
 13 *meaning given such term in section 1861(e) of the So-*
 14 *cial Security Act (42 U.S.C. 1395x(e)).*

15 (2) *INDIAN TRIBE; TRIBAL ORGANIZATION.*—*The*
 16 *terms “Indian tribe” and “tribal organization” have*
 17 *the meanings given such terms in section 4 of the In-*
 18 *Indian Health Care Improvement Act (25 U.S.C. 1603).*

19 (3) *PROVIDER.*—*The term “provider” includes a*
 20 *physician, any other health care professional licensed*
 21 *under State law, and any other entity that furnishes*
 22 *emergency health services, including ambulance serv-*
 23 *ices.*

24 (4) *SECRETARY.*—*The term “Secretary” means*
 25 *the Secretary of Health and Human Services.*

1 (5) *STATE*.—*The term “State” means the 50*
 2 *States and the District of Columbia.*

3 **SEC. 611. INCREASE IN APPROPRIATION TO THE HEALTH**
 4 **CARE FRAUD AND ABUSE CONTROL AC-**
 5 **COUNT.**

6 *Section 1817(k)(3)(A) (42 U.S.C. 1395i(k)(3)(A)) is*
 7 *amended—*

8 (1) *in clause (i)—*

9 (A) *in subclause (II), by striking “and” at*
 10 *the end; and*

11 (B) *by striking subclause (III), and insert-*
 12 *ing the following new subclauses:*

13 “(III) *for fiscal year 2004, the*
 14 *limit for fiscal year 2003 increased by*
 15 *\$10,000,000;*

16 “(IV) *for fiscal year 2005, the*
 17 *limit for fiscal year 2003 increased by*
 18 *\$15,000,000;*

19 “(V) *for fiscal year 2006, the*
 20 *limit for fiscal year 2003 increased by*
 21 *\$25,000,000; and*

22 “(VI) *for each fiscal year after fis-*
 23 *cal year 2006, the limit for fiscal year*
 24 *2003.”; and*

25 (2) *in clause (ii)—*

1 (A) in subclause (VI), by striking “and” at
2 the end;

3 (B) in subclause (VII)—

4 (i) by striking “each fiscal year after
5 fiscal year 2002” and inserting “fiscal year
6 2003”; and

7 (ii) by striking the period and insert-
8 ing a semicolon; and

9 (3) by adding at the end the following:

10 “(VIII) for fiscal year 2004,
11 \$170,000,000;

12 “(IX) for fiscal year 2005,
13 \$175,000,000;

14 “(X) for fiscal year 2006,
15 \$185,000,000; and

16 “(XI) for each fiscal year after fis-
17 cal year 2006, not less than
18 \$150,000,000 and not more than
19 \$160,000,000.”.

20 **SEC. 612. INCREASE IN CIVIL PENALTIES UNDER THE FALSE**
21 **CLAIMS ACT.**

22 (a) *IN GENERAL.*—Section 3729(a) of title 31, United
23 States Code, is amended—

24 (1) by striking “\$5,000” and inserting “\$7,500”;
25 and

1 (2) *by striking “\$10,000” and inserting*
 2 *“\$15,000”.*

3 (b) *EFFECTIVE DATE.*—*The amendments made by sub-*
 4 *section (a) shall apply to violations occurring on or after*
 5 *January 1, 2004.*

6 **SEC. 613. INCREASE IN CIVIL MONETARY PENALTIES**
 7 **UNDER THE SOCIAL SECURITY ACT.**

8 (a) *IN GENERAL.*—*Section 1128A(a) (42 U.S.C.*
 9 *1320a–7a(a)), in the matter following paragraph (7), is*
 10 *amended—*

11 (1) *by striking “\$10,000” each place it appears*
 12 *and inserting “\$12,500”;*

13 (2) *by striking “\$15,000” and inserting*
 14 *“\$18,750”; and*

15 (3) *striking “\$50,000” and inserting “\$62,500”.*

16 (b) *EFFECTIVE DATE.*—*The amendments made by sub-*
 17 *section (a) shall apply to violations occurring on or after*
 18 *January 1, 2004.*

19 **SEC. 614. EXTENSION OF CUSTOMS USER FEES.**

20 *Section 13031(j)(3) of the Consolidated Omnibus*
 21 *Budget Reconciliation Act of 1985 (19 U.S.C. 58c(j)(3)) is*
 22 *amended by striking “September 30, 2003” and inserting*
 23 *“September 30, 2013”.*

1 **SEC. 615. REIMBURSEMENT FOR FEDERALLY QUALIFIED**
 2 **HEALTH CENTERS PARTICIPATING IN MEDI-**
 3 **CARE MANAGED CARE.**

4 *(a) REIMBURSEMENT.—*

5 *(1) IN GENERAL.—Section 1833(a)(3) (42 U.S.C.*
 6 *1395l(a)(3)) is amended to read as follows:*

7 *“(3) in the case of services described in section*
 8 *1832(a)(2)(D)—*

9 *“(A) except as provided in subparagraph*
 10 *(B), the costs which are reasonable and related*
 11 *to the cost of furnishing such services or which*
 12 *are based on such other tests of reasonableness as*
 13 *the Secretary may prescribe in regulations, in-*
 14 *cluding those authorized under section*
 15 *1861(v)(1)(A), less the amount a provider may*
 16 *charge as described in clause (ii) of section*
 17 *1866(a)(2)(A), but in no case may the payment*
 18 *for such services (other than for items and serv-*
 19 *ices described in section 1861(s)(10)(A)) exceed*
 20 *80 percent of such costs; or*

21 *“(B) with respect to the services described*
 22 *in clause (ii) of section 1832(a)(2)(D) that are*
 23 *furnished to an individual enrolled with a*
 24 *MedicareAdvantage plan under part C pursuant*
 25 *to a written agreement described in section*
 26 *1853(j), the amount by which—*

1 “(i) the amount of payment that would
 2 have otherwise been provided under sub-
 3 paragraph (A) (calculated as if ‘100 per-
 4 cent’ were substituted for ‘80 percent’ in
 5 such subparagraph) for such services if the
 6 individual had not been so enrolled; exceeds

7 “(ii) the amount of the payments re-
 8 ceived under such written agreement for
 9 such services (not including any financial
 10 incentives provided for in such agreement
 11 such as risk pool payments, bonuses, or
 12 withholds),

13 less the amount the Federally qualified health
 14 center may charge as described in section
 15 1857(e)(3)(C);”.

16 (b) CONTINUATION OF MEDICAREADVANTAGE MONTH-
 17 LY PAYMENTS.—

18 (1) IN GENERAL.—Section 1853 (42 U.S.C.
 19 1395w–23), as amended by this Act, is amended by
 20 adding at the end the following new subsection:

21 “(j) PAYMENT RULE FOR FEDERALLY QUALIFIED
 22 HEALTH CENTER SERVICES.—If an individual who is en-
 23 rolled with a MedicareAdvantage plan under this part re-
 24 ceives a service from a Federally qualified health center that
 25 has a written agreement with such plan for providing such

1 *a service (including any agreement required under section*
 2 *1857(e)(3))—*

3 *“(1) the Secretary shall pay the amount deter-*
 4 *mined under section 1833(a)(3)(B) directly to the*
 5 *Federally qualified health center not less frequently*
 6 *than quarterly; and*

7 *“(2) the Secretary shall not reduce the amount*
 8 *of the monthly payments to the MedicareAdvantage*
 9 *plan made under section 1853(a) as a result of the*
 10 *application of paragraph (1).”.*

11 *(2) CONFORMING AMENDMENTS.—*

12 *(A) Paragraphs (1) and (2) of section*
 13 *1851(i) (42 U.S.C. 1395w–21(i)(1)), as amended*
 14 *by this Act, are each amended by inserting*
 15 *“1853(j),” after “1853(i),”.*

16 *(B) Section 1853(c)(5) is amended by strik-*
 17 *ing “subsections (a)(3)(C)(iii) and (i)” and in-*
 18 *serting “subsections (a)(3)(C)(iii), (i), and*
 19 *(j)(1).”.*

20 *(c) ADDITIONAL MEDICAREADVANTAGE CONTRACT RE-*
 21 *QUIREMENTS.—Section 1857(e) (42 U.S.C. 1395w–27(e)) is*
 22 *amended by adding at the end the following new paragraph:*

23 *“(3) AGREEMENTS WITH FEDERALLY QUALIFIED*
 24 *HEALTH CENTERS.—*

1 “(A) *PAYMENT LEVELS AND AMOUNTS.*—A
 2 *contract under this part shall require the*
 3 *MedicareAdvantage plan to provide, in any con-*
 4 *tract between the plan and a Federally qualified*
 5 *health center, for a level and amount of payment*
 6 *to the Federally qualified health center for serv-*
 7 *ices provided by such health center that is not*
 8 *less than the level and amount of payment that*
 9 *the plan would make for such services if the serv-*
 10 *ices had been furnished by a provider of services*
 11 *that was not a Federally qualified health center.*

12 “(B) *COST-SHARING.*—Under the written
 13 *agreement described in subparagraph (A), a Fed-*
 14 *erally qualified health center must accept the*
 15 *MedicareAdvantage contract price plus the Fed-*
 16 *eral payment provided for in section*
 17 *1833(a)(3)(B) as payment in full for services*
 18 *covered by the contract, except that such a health*
 19 *center may collect any amount of cost-sharing*
 20 *permitted under the contract under this part, so*
 21 *long as the amounts of any deductible, coinsur-*
 22 *ance, or copayment comply with the require-*
 23 *ments under section 1854(e).”.*

1 (d) *SAFE HARBOR FROM ANTIKICKBACK PROHIBI-*
 2 *TION.—Section 1128B(b)(3) (42 U.S.C. 1320a–7b(b)(3)) is*
 3 *amended—*

4 (1) *in subparagraph (E), by striking “and” after*
 5 *the semicolon at the end;*

6 (2) *in subparagraph (F), by striking the period*
 7 *at the end and inserting “; and”; and*

8 (3) *by adding at the end the following new sub-*
 9 *paragraph:*

10 “(G) *any remuneration between a Federally*
 11 *qualified health center (or an entity controlled*
 12 *by such a health center) and a*
 13 *MedicareAdvantage plan pursuant to the written*
 14 *agreement described in section 1853(j).”.*

15 (e) *EFFECTIVE DATE.—The amendments made by this*
 16 *section shall apply to services provided on or after January*
 17 *1, 2006, and contract years beginning on or after such date.*

18 **SEC. 616. PROVISION OF INFORMATION ON ADVANCE DI-**
 19 **RECTIVES.**

20 *Section 1804(c) of the Social Security Act (42 U.S.C.*
 21 *1395b-2(c)) is amended—*

22 (1) *by redesignating paragraphs (1) through (4)*
 23 *as subparagraphs (A) through (D), respectively;*

1 (2) *in the matter preceding subparagraph (A), as*
 2 *so redesignated, by striking “The notice” and insert-*
 3 *ing “(1) The notice”; and*

4 (3) *by adding at the end the following:*

5 “(2)(A) *The Secretary shall annually provide each*
 6 *medicare beneficiary with information concerning advance*
 7 *directives. Such information shall be provided by the Sec-*
 8 *retary as part of the Medicare and You handbook that is*
 9 *provided to each such beneficiary. Such handbook shall in-*
 10 *clude a separate section on advanced directives and specific*
 11 *details on living wills and the durable power of attorney*
 12 *for health care. The Secretary shall ensure that the intro-*
 13 *ductory letter that accompanies such handbook contain a*
 14 *statement concerning the inclusion of such information.*

15 “(B) *In this section:*

16 “(i) *The term ‘advance directive’ has the mean-*
 17 *ing given such term in section 1866(f)(3).*

18 “(ii) *The term ‘medicare beneficiary’ means an*
 19 *individual who is entitled to, or enrolled for, benefits*
 20 *under part A or enrolled under part B, of this title.”.*

21 **SEC. 617. SENSE OF THE SENATE REGARDING IMPLEMENTA-**
 22 **TION OF THE PRESCRIPTION DRUG AND**
 23 **MEDICARE IMPROVEMENT ACT OF 2003.**

24 (a) *IN GENERAL.—It is the sense of the Senate that*
 25 *the Committee on Finance of the Senate should hold not*

1 *less than 4 hearings to monitor implementation of the Pre-*
 2 *scription Drug and Medicare Improvement Act of 2003*
 3 *(hereinafter in this section referred to as the “Act”) during*
 4 *which the Secretary or his designee should testify before the*
 5 *Committee.*

6 (b) *INITIAL HEARING.—It is the sense of the Senate*
 7 *that the first hearing described in subsection (a) should be*
 8 *held not later than 60 days after the date of the enactment*
 9 *the Act. At the hearing, the Secretary or his designee should*
 10 *submit written testimony and testify before the Committee*
 11 *on Finance of the Senate on the following issues:*

12 (1) *The progress toward implementation of the*
 13 *prescription drug discount card under section 111 of*
 14 *the Act.*

15 (2) *Development of the blueprint that will direct*
 16 *the implementation of the provisions of the Act, in-*
 17 *cluding the implementation of title I (Medicare Pre-*
 18 *scription Drug Benefit), title II (Medicare Advantage),*
 19 *and title III (Center for Medicare Choices) of the Act.*

20 (3) *Any problems that will impede the timely*
 21 *implementation of the Act.*

22 (4) *The overall progress toward implementation*
 23 *of the Act.*

24 (c) *SUBSEQUENT HEARINGS.—It is the sense of the*
 25 *Senate that the additional hearings described in subsection*

1 (a) should be held in each of May 2004, October 2004, and
 2 May 2005. At each hearing, the Secretary or his designee
 3 should submit written testimony and testify before the Com-
 4 mittee on Finance of the Senate on the following issues:

5 (1) Progress on implementation of title I (Medi-
 6 care Prescription Drug Benefit), title II
 7 (MedicareAdvantage), and title III (Center for Medi-
 8 care Choices) of the Act.

9 (2) Any problems that will impede timely imple-
 10 mentation of the Act.

11 **SEC. 618. EXTENSION OF MUNICIPAL HEALTH SERVICE**
 12 **DEMONSTRATION PROJECTS.**

13 The last sentence of section 9215(a) of the Consolidated
 14 Omnibus Budget Reconciliation Act of 1985 (42 U.S.C.
 15 1395b–1 note), as previously amended, is amended by strik-
 16 ing “December 31, 2004, and inserting “December 31, 2006.

17 **SEC. 619. STUDY ON MAKING PRESCRIPTION PHARMA-**
 18 **CEUTICAL INFORMATION ACCESSIBLE FOR**
 19 **BLIND AND VISUALLY-IMPAIRED INDIVID-**
 20 **UALS.**

21 (a) *STUDY.*—

22 (1) *IN GENERAL.*—The Secretary of Health and
 23 Human Services shall undertake a study of how to
 24 make prescription pharmaceutical information, in-

cluding drug labels and usage instructions, accessible to blind and visually-impaired individuals.

(2) *STUDY TO INCLUDE EXISTING AND EMERGING TECHNOLOGIES.*—The study under paragraph (1) shall include a review of existing and emerging technologies, including assistive technology, that makes essential information on the content and prescribed use of pharmaceutical medicines available in a usable format for blind and visually-impaired individuals.

(b) *REPORT.*—

(1) *IN GENERAL.*—Not later than 18 months after the date of the enactment of this Act, the Secretary of Health and Human Services shall submit a report to Congress on the study required under subsection (a).

(2) *CONTENTS OF REPORT.*—The report required under subsection (a) shall include recommendations for the implementation of usable formats for making prescription pharmaceutical information available to blind and visually-impaired individuals and an estimate of the costs associated with the implementation of each format.

**SEC. 620. HEALTH CARE THAT WORKS FOR ALL AMERICANS—
CITIZENS HEALTH CARE WORKING GROUP.**

(a) *FINDINGS.*—Congress finds the following:

1 (1) *In order to improve the health care system,*
2 *the American public must engage in an informed na-*
3 *tional public debate to make choices about the services*
4 *they want covered, what health care coverage they*
5 *want, and how they are willing to pay for coverage.*

6 (2) *More than a trillion dollars annually is*
7 *spent on the health care system, yet—*

8 (A) *41,000,000 Americans are uninsured;*

9 (B) *insured individuals do not always have*
10 *access to essential, effective services to improve*
11 *and maintain their health; and*

12 (C) *employers, who cover over 170,000,000*
13 *Americans, find providing coverage increasingly*
14 *difficult because of rising costs and double digit*
15 *premium increases.*

16 (3) *Despite increases in medical care spending*
17 *that are greater than the rate of inflation, population*
18 *growth, and Gross Domestic Product growth, there*
19 *has not been a commensurate improvement in our*
20 *health status as a nation.*

21 (4) *Health care costs for even just 1 member of*
22 *a family can be catastrophic, resulting in medical*
23 *bills potentially harming the economic stability of the*
24 *entire family.*

1 (5) *Common life occurrences can jeopardize the*
 2 *ability of a family to retain private coverage or jeop-*
 3 *ardize access to public coverage.*

4 (6) *Innovations in health care access, coverage,*
 5 *and quality of care, including the use of technology,*
 6 *have often come from States, local communities, and*
 7 *private sector organizations, but more creative poli-*
 8 *cies could tap this potential.*

9 (7) *Despite our Nation's wealth, the health care*
 10 *system does not provide coverage to all Americans*
 11 *who want it.*

12 (b) *PURPOSES.—The purposes of this Act are—*

13 (1) *to provide for a nationwide public debate*
 14 *about improving the health care system to provide*
 15 *every American with the ability to obtain quality, af-*
 16 *fordable health care coverage; and*

17 (2) *to provide for a vote by Congress on the rec-*
 18 *ommendations that result from the debate.*

19 (c) *ESTABLISHMENT.—The Secretary, acting through*
 20 *the Agency for Healthcare Research and Quality, shall es-*
 21 *tablish an entity to be known as the Citizens' Health Care*
 22 *Working Group (referred to in this Act as the "Working*
 23 *Group").*

24 (d) *APPOINTMENT.—Not later than 45 days after the*
 25 *date of enactment of this Act, the Speaker and Minority*

1 *Leader of the House of Representatives and the Majority*
 2 *Leader and Minority Leader of the Senate (in this section*
 3 *referred to as the “leadership”) shall each appoint individ-*
 4 *uals to serve as members of the Working Group in accord-*
 5 *ance with subsections (e), (f), and (g).*

6 (e) *MEMBERSHIP CRITERIA.—*

7 (1) *APPOINTED MEMBERS.—*

8 (A) *SEPARATE APPOINTMENTS.—The*
 9 *Speaker of the House of Representatives jointly*
 10 *with the Minority Leader of the House of Rep-*
 11 *resentatives, and the Majority Leader of the Sen-*
 12 *ate jointly with the Minority Leader of the Sen-*
 13 *ate, shall each appoint 1 member of the Working*
 14 *Group described in subparagraphs (A), (G), (J),*
 15 *(K), and (M) of paragraph (2).*

16 (B) *JOINT APPOINTMENTS.—Members of the*
 17 *Working Group described in subparagraphs (B),*
 18 *(C), (D), (E), (F), (I), and (N) of paragraph (2)*
 19 *shall be appointed jointly by the leadership.*

20 (C) *COMBINED APPOINTMENTS.—Members*
 21 *of the Working Group described in subpara-*
 22 *graphs (H) and (L) shall be appointed in the fol-*
 23 *lowing manner:*

1 (i) *One member of the Working Group*
 2 *in each of such subparagraphs shall be ap-*
 3 *pointed jointly by the leadership.*

4 (ii) *The remaining appointments of*
 5 *the members in each of such subparagraphs*
 6 *shall be divided equally such that the*
 7 *Speaker of the House of Representatives*
 8 *jointly with the Minority Leader of the*
 9 *House of Representatives, and the Majority*
 10 *Leader of the Senate jointly with the Minor-*
 11 *ity Leader of the Senate each appoint an*
 12 *equal number of members.*

13 (2) *CATEGORIES OF APPOINTED MEMBERS.—*
 14 *Members of the Working Group shall be appointed as*
 15 *follows:*

16 (A) *2 members shall be patients or family*
 17 *members of patients who, at least 1 year prior*
 18 *to the date of enactment of this Act, have had no*
 19 *health insurance.*

20 (B) *1 member shall be a representative of*
 21 *children.*

22 (C) *1 member shall be a representative of*
 23 *the mentally ill.*

24 (D) *1 member shall be a representative of*
 25 *the disabled.*

1 (E) 1 member shall be over the age of 65
 2 and a beneficiary under the medicare program
 3 established under title XVIII of the Social Secu-
 4 rity Act (42 U.S.C. 1395 et seq.).

5 (F) 1 member shall be a recipient of benefits
 6 under the medicaid program under title XIX of
 7 the Social Security Act (42 U.S.C. 1396 et seq.).

8 (G) 2 members shall be State health offi-
 9 cials.

10 (H) 3 members shall be employers,
 11 including—

12 (i) 1 large employer (an employer who
 13 employed 50 or more employees on business
 14 days during the preceding calendar year
 15 and who employed at least 50 employees on
 16 the first of the year);

17 (ii) 1 small employer (an employer
 18 who employed an average of at least 2 em-
 19 ployees but less than 50 employees on busi-
 20 ness days in the preceding calendar year
 21 and who employs at least 2 employees on
 22 the first of the year); and

23 (iii) 1 multi-state employer.

24 (I) 1 member shall be a representative of
 25 labor.

1 (J) 2 members shall be health insurance
2 issuers.

3 (K) 2 members shall be health care pro-
4 viders.

5 (L) 5 members shall be appointed as fol-
6 lows:

7 (i) 1 economist.

8 (ii) 1 academician.

9 (iii) 1 health policy researcher.

10 (iv) 1 individual with expertise in
11 pharmacoeconomics.

12 (v) 1 health technology expert.

13 (M) 2 members shall be representatives of
14 community leaders who have developed State or
15 local community solutions to the problems ad-
16 dressed by the Working Group.

17 (N) 1 member shall be a representative of a
18 medical school.

19 (3) SECRETARY.—The Secretary, or the designee
20 of the Secretary, shall be a member of the Working
21 Group.

22 (f) PROHIBITED APPOINTMENTS.—Members of the
23 Working Group shall not include members of Congress or
24 other elected government officials (Federal, State, or local)
25 other than those individuals specified in subsection (e). To

1 *the extent possible, individuals appointed to the Working*
 2 *Group shall have used the health care system within the*
 3 *previous 2 years and shall not be paid employees or rep-*
 4 *resentatives of associations or advocacy organizations in-*
 5 *volved in the health care system.*

6 (g) *APPOINTMENT CRITERIA.*—

7 (1) *HOUSE OF REPRESENTATIVES.*—*The Speaker*
 8 *and Minority Leader of the House of Representatives*
 9 *shall make the appointments described in subsection*
 10 *(d) in consultation with the chairperson and ranking*
 11 *member of the following committees of the House of*
 12 *Representatives:*

13 (A) *The Committee on Ways and Means.*

14 (B) *The Committee on Energy and Com-*
 15 *merce.*

16 (C) *The Committee on Education and the*
 17 *Workforce.*

18 (2) *SENATE.*—*The Majority Leader and Minor-*
 19 *ity Leader of the Senate shall make the appointments*
 20 *described in subsection (d) in consultation with the*
 21 *chairperson and ranking member of the following*
 22 *committees of the Senate:*

23 (A) *The Committee on Finance.*

24 (B) *The Committee on Health, Education,*
 25 *Labor, and Pensions.*

1 (h) *PERIOD OF APPOINTMENT.*—*Members of the Work-*
 2 *ing Group shall be appointed for a term of 2 years. Such*
 3 *term is renewable and any vacancies shall not affect the*
 4 *power and duties of the Working Group but shall be filled*
 5 *in the same manner as the original appointment.*

6 (i) *APPOINTMENT OF THE CHAIRPERSON.*—*Not later*
 7 *than 15 days after the date on which all members of the*
 8 *Working Group have been appointed under subsection (d),*
 9 *the leadership shall make a joint designation of the chair-*
 10 *person of the Working Group. If the leadership fails to make*
 11 *such designation within such time period, the Working*
 12 *Group Members shall, not later than 10 days after the end*
 13 *of such time period, designate a chairperson by majority*
 14 *vote.*

15 (j) *SUBCOMMITTEES.*—*The Working Group may estab-*
 16 *lish subcommittees if doing so increases the efficiency of the*
 17 *Working Group in completing its tasks.*

18 (k) *DUTIES.*—

19 (1) *HEARINGS.*—*Not later than 90 days after the*
 20 *date of appointment of the chairperson under sub-*
 21 *section (i), the Working Group shall hold hearings to*
 22 *examine—*

23 (A) *the capacity of the public and private*
 24 *health care systems to expand coverage options;*

1 (B) the cost of health care and the effective-
2 ness of care provided at all stages of disease;

3 (C) innovative State strategies used to ex-
4 pand health care coverage and lower health care
5 costs;

6 (D) local community solutions to accessing
7 health care coverage;

8 (E) efforts to enroll individuals currently el-
9 igible for public or private health care coverage;

10 (F) the role of evidence-based medical prac-
11 tices that can be documented as restoring, main-
12 taining, or improving a patient's health, and the
13 use of technology in supporting providers in im-
14 proving quality of care and lowering costs; and

15 (G) strategies to assist purchasers of health
16 care, including consumers, to become more aware
17 of the impact of costs, and to lower the costs of
18 health care.

19 (2) *ADDITIONAL HEARINGS.*—The Working
20 Group may hold additional hearings on subjects other
21 than those listed in paragraph (1) so long as such
22 hearings are determined to be necessary by the Work-
23 ing Group in carrying out the purposes of this Act.
24 Such additional hearings do not have to be completed
25 within the time period specified in paragraph (1) but

1 *shall not delay the other activities of the Working*
 2 *Group under this section.*

3 (3) *THE HEALTH REPORT TO THE AMERICAN*
 4 *PEOPLE.*—*Not later than 90 days after the hearings*
 5 *described in paragraphs (1) and (2) are completed,*
 6 *the Working Group shall prepare and make available*
 7 *to health care consumers through the Internet and*
 8 *other appropriate public channels, a report to be enti-*
 9 *tled, “The Health Report to the American People”.*
 10 *Such report shall be understandable to the general*
 11 *public and include—*

12 (A) *a summary of—*

13 (i) *health care and related services that*
 14 *may be used by individuals throughout*
 15 *their life span;*

16 (ii) *the cost of health care services and*
 17 *their medical effectiveness in providing bet-*
 18 *ter quality of care for different age groups;*

19 (iii) *the source of coverage and pay-*
 20 *ment, including reimbursement, for health*
 21 *care services;*

22 (iv) *the reasons people are uninsured*
 23 *or underinsured and the cost to taxpayers,*
 24 *purchasers of health services, and commu-*

1 nities when Americans are uninsured or
2 underinsured;

3 (v) the impact on health care outcomes
4 and costs when individuals are treated in
5 all stages of disease;

6 (vi) health care cost containment strat-
7 egies; and

8 (vii) information on health care needs
9 that need to be addressed;

10 (B) examples of community strategies to
11 provide health care coverage or access;

12 (C) information on geographic-specific
13 issues relating to health care;

14 (D) information concerning the cost of care
15 in different settings, including institutional-
16 based care and home and community-based care;

17 (E) a summary of ways to finance health
18 care coverage; and

19 (F) the role of technology in providing fu-
20 ture health care including ways to support the
21 information needs of patients and providers.

22 (4) COMMUNITY MEETINGS.—

23 (A) IN GENERAL.—Not later than 1 year
24 after the date of enactment of this Act, the Work-
25 ing Group shall initiate health care community

1 *meetings throughout the United States (in this*
2 *section referred to as “community meetings”).*
3 *Such community meetings may be geographi-*
4 *cally or regionally based and shall be completed*
5 *within 180 days after the initiation of the first*
6 *meeting.*

7 *(B) NUMBER OF MEETINGS.—The Working*
8 *Group shall hold a sufficient number of commu-*
9 *nity meetings in order to receive information*
10 *that reflects—*

11 *(i) the geographic differences through-*
12 *out the United States;*

13 *(ii) diverse populations; and*

14 *(iii) a balance among urban and rural*
15 *populations.*

16 *(C) MEETING REQUIREMENTS.—*

17 *(i) FACILITATOR.—A State health offi-*
18 *cer may be the facilitator at the community*
19 *meetings.*

20 *(ii) ATTENDANCE.—At least 1 member*
21 *of the Working Group shall attend and serve*
22 *as chair of each community meeting. Other*
23 *members may participate through inter-*
24 *active technology.*

1 (iii) *TOPICS.*—*The community meet-*
 2 *ings shall, at a minimum, address the fol-*
 3 *lowing issues:*

4 (I) *The optimum way to balance*
 5 *costs and benefits so that affordable*
 6 *health coverage is available to as many*
 7 *people as possible.*

8 (II) *The identification of services*
 9 *that provide cost-effective, essential*
 10 *health care services to maintain and*
 11 *improve health and which should be*
 12 *included in health care coverage.*

13 (III) *The cost of providing in-*
 14 *creased benefits.*

15 (IV) *The mechanisms to finance*
 16 *health care coverage, including defin-*
 17 *ing the appropriate financial role for*
 18 *individuals, businesses, and govern-*
 19 *ment.*

20 (iv) *INTERACTIVE TECHNOLOGY.*—*The*
 21 *Working Group may encourage public par-*
 22 *ticipation in community meetings through*
 23 *interactive technology and other means as*
 24 *determined appropriate by the Working*
 25 *Group.*

1 (D) *INTERIM REQUIREMENTS.*—Not later
2 than 180 days after the date of completion of the
3 community meetings, the Working Group shall
4 prepare and make available to the public
5 through the Internet and other appropriate pub-
6 lic channels, an interim set of recommendations
7 on health care coverage and ways to improve
8 and strengthen the health care system based on
9 the information and preferences expressed at the
10 community meetings. There shall be a 90-day
11 public comment period on such recommenda-
12 tions.

13 (l) *RECOMMENDATIONS.*—Not later than 120 days
14 after the expiration of the public comment period described
15 in subsection (k)(4)(D), the Working Group shall submit to
16 Congress and the President a final set of recommendations.

17 (m) *ADMINISTRATION.*—

18 (1) *EXECUTIVE DIRECTOR.*—There shall be an
19 Executive Director of the Working Group who shall be
20 appointed by the chairperson of the Working Group
21 in consultation with the members of the Working
22 Group.

23 (2) *COMPENSATION.*—While serving on the busi-
24 ness of the Working Group (including travel time), a
25 member of the Working Group shall be entitled to

1 *compensation at the per diem equivalent of the rate*
 2 *provided for level IV of the Executive Schedule under*
 3 *section 5315 of title 5, United States Code, and while*
 4 *so serving away from home and the member's regular*
 5 *place of business, a member may be allowed travel ex-*
 6 *penses, as authorized by the chairperson of the Work-*
 7 *ing Group. For purposes of pay and employment ben-*
 8 *efits, rights, and privileges, all personnel of the Work-*
 9 *ing Group shall be treated as if they were employees*
 10 *of the Senate.*

11 (3) *INFORMATION FROM FEDERAL AGENCIES.—*
 12 *The Working Group may secure directly from any*
 13 *Federal department or agency such information as*
 14 *the Working Group considers necessary to carry out*
 15 *this Act. Upon request of the Working Group, the*
 16 *head of such department or agency shall furnish such*
 17 *information.*

18 (4) *POSTAL SERVICES.—The Working Group*
 19 *may use the United States mails in the same manner*
 20 *and under the same conditions as other departments*
 21 *and agencies of the Federal Government.*

22 (n) *DETAIL.—Not more than 10 Federal Government*
 23 *employees employed by the Department of Labor and 10*
 24 *Federal Government employees employed by the Depart-*
 25 *ment of Health and Human Services may be detailed to*

1 *the Working Group under this section without further reim-*
 2 *bursement. Any detail of an employee shall be without*
 3 *interruption or loss of civil service status or privilege.*

4 (o) *TEMPORARY AND INTERMITTENT SERVICES.*—*The*
 5 *chairperson of the Working Group may procure temporary*
 6 *and intermittent services under section 3109(b) of title 5,*
 7 *United States Code, at rates for individuals which do not*
 8 *exceed the daily equivalent of the annual rate of basic pay*
 9 *prescribed for level V of the Executive Schedule under sec-*
 10 *tion 5316 of such title.*

11 (p) *ANNUAL REPORT.*—*Not later than 1 year after the*
 12 *date of enactment of this Act, and annually thereafter dur-*
 13 *ing the existence of the Working Group, the Working Group*
 14 *shall report to Congress and make public a detailed descrip-*
 15 *tion of the expenditures of the Working Group used to carry*
 16 *out its duties under this section.*

17 (q) *SUNSET OF WORKING GROUP.*—*The Working*
 18 *Group shall terminate when the report described in sub-*
 19 *section (l) is submitted to Congress.*

20 (r) *ADMINISTRATION REVIEW AND COMMENTS.*—*Not*
 21 *later than 45 days after receiving the final recommenda-*
 22 *tions of the Working Group under subsection (l), the Presi-*
 23 *dent shall submit a report to Congress which shall*
 24 *contain—*

1 (1) *additional views and comments on such rec-*
 2 *ommendations; and*

3 (2) *recommendations for such legislation and ad-*
 4 *ministrative actions as the President considers appro-*
 5 *priate.*

6 (s) *REQUIRED CONGRESSIONAL ACTION.*—*Not later*
 7 *than 45 days after receiving the report submitted by the*
 8 *President under subsection (r), each committee of jurisdic-*
 9 *tion of Congress shall hold at least 1 hearing on such report*
 10 *and on the final recommendations of the Working Group*
 11 *submitted under subsection (l).*

12 (t) *AUTHORIZATION OF APPROPRIATIONS.*—

13 (1) *IN GENERAL.*—*There are authorized to be*
 14 *appropriated to carry out this Act, other than sub-*
 15 *section (k)(3), \$3,000,000 for each of fiscal years*
 16 *2004, 2005, and 2006.*

17 (2) *HEALTH REPORT TO THE AMERICAN PEO-*
 18 *PLE.*—*There are authorized to be appropriated for the*
 19 *preparation and dissemination of the Health Report*
 20 *to the American People described in subsection (k)(3),*
 21 *such sums as may be necessary for the fiscal year in*
 22 *which the report is required to be submitted.*

1 **SEC. 621. GAO STUDY OF PHARMACEUTICAL PRICE CON-**
2 **TROLS AND PATENT PROTECTIONS IN THE G-**
3 **7 COUNTRIES.**

4 (a) *STUDY.*—*The Comptroller General of the United*
5 *States shall conduct a study of price controls imposed on*
6 *pharmaceuticals in France, Germany, Italy, Japan, the*
7 *United Kingdom and Canada to review the impact such*
8 *regulations have on consumers, including American con-*
9 *sumers, and on innovation in medicine. Such study shall*
10 *include—*

11 (1) *the pharmaceutical price control structure in*
12 *each country for a wide range of pharmaceuticals,*
13 *compared with average pharmaceutical prices paid by*
14 *Americans covered by private sector health insurance;*

15 (2) *the proportion of the cost for innovation*
16 *borne by American consumers, compared with con-*
17 *sumers in the other six countries;*

18 (3) *a review of how closely the observed prices in*
19 *regulated markets correspond to the prices that effi-*
20 *ciently distribute common costs of production*
21 *(“Ramsey prices”);*

22 (4) *a review of any peer-reviewed literature that*
23 *might show the health consequences to patients in the*
24 *listed countries that result from the absence or de-*
25 *layed introduction of medicines, including the cost of*

1 *not having access to medicines, in terms of lower life*
2 *expectancy and lower quality of health;*

3 *(5) the impact on American consumers, in terms*
4 *of reduced research into new or improved pharma-*
5 *ceuticals (including the cost of delaying the introduc-*
6 *tion of a significant advance in certain major dis-*
7 *eases), if similar price controls were adopted in the*
8 *United States;*

9 *(6) the existing standards under international*
10 *conventions, including the World Trade Organization*
11 *and the North American Free Trade Agreement, re-*
12 *garding regulated pharmaceutical prices, including*
13 *any restrictions on anti-competitive laws that might*
14 *apply to price regulations and how economic harm*
15 *caused to consumers in markets without price regula-*
16 *tions may be remedied;*

17 *(7) in parallel trade regimes, how much of the*
18 *price difference between countries in the European*
19 *Union is captured by middlemen and how much goes*
20 *to benefit patients and health systems where parallel*
21 *importing is significant; and*

22 *(8) how much cost is imposed on the owner of a*
23 *property right from counterfeiting and from inter-*
24 *national violation of intellectual property rights for*
25 *prescription medicines.*

1 (b) *REPORT*.—Not later than 1 year after the date of
 2 enactment of this Act, the Comptroller General of the United
 3 States shall submit to Congress a report on the study con-
 4 ducted under subsection (a).

5 **SEC. 622. SENSE OF THE SENATE CONCERNING MEDICARE**
 6 **PAYMENT UPDATE FOR PHYSICIANS AND**
 7 **OTHER HEALTH PROFESSIONALS.**

8 (a) *FINDINGS*.—The Senate makes the following find-
 9 ings:

10 (1) *The formula by which medicare payments*
 11 *are updated each year for services furnished by physi-*
 12 *cians and other health professionals is fundamentally*
 13 *flawed.*

14 (2) *The flawed physician payment update for-*
 15 *mula is causing a continuing physician payment cri-*
 16 *sis, and, without congressional action, medicare pay-*
 17 *ment rates for physicians and other practitioners are*
 18 *predicted to fall by 4.2 percent in 2004.*

19 (3) *A physician payment cut in 2004 would be*
 20 *the fifth cut since 1991, and would be on top of a 5.4*
 21 *percent cut in 2002, with additional cuts estimated*
 22 *for 2005, 2006, and 2007; from 1991–2003, payment*
 23 *rates for physicians and health professionals fell 14*
 24 *percent behind practice cost inflation as measured by*
 25 *medicare’s own conservative estimates.*

15 *SEC. 623. RESTORATION OF FEDERAL HOSPITAL INSUR-*
16 *ANCE TRUST FUND.*

(1) *CLERICAL ERROR.*—The term “clerical error” means the failure that occurred on April 15, 2001, to have transferred the correct amount from the general fund of the Treasury to the Trust Fund.

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1 (b) *CORRECTION OF TRUST FUND HOLDINGS.*—

2 (1) *IN GENERAL.*—Not later than 120 days after
 3 the date of enactment of this Act, the Secretary of the
 4 Treasury shall take the actions described in para-
 5 graph (2) with respect to the Trust Fund with the
 6 goal being that, after such actions are taken, the hold-
 7 ings of the Trust Fund will replicate, to the extent
 8 practicable in the judgment of the Secretary of the
 9 Treasury, in consultation with the Secretary of
 10 Health and Human Services, the holdings that would
 11 have been held by the Trust Fund if the clerical error
 12 had not occurred.

13 (2) *OBLIGATIONS ISSUED AND REDEEMED.*—The
 14 Secretary of the Treasury shall—

15 (A) issue to the Trust Fund obligations
 16 under chapter 31 of title 31, United States Code,
 17 that bear issue dates, interest rates, and matu-
 18 rity dates that are the same as those for the obli-
 19 gations that—

20 (i) would have been issued to the Trust
 21 Fund if the clerical error had not occurred;

22 or

23 (ii) were issued to the Trust Fund and
 24 were redeemed by reason of the clerical
 25 error; and

1 (B) redeem from the Trust Fund obligations
 2 that would have been redeemed from the Trust
 3 Fund if the clerical error had not occurred.

4 (c) *APPROPRIATION.*—Not later than 120 days after
 5 the date of enactment of this Act, there is appropriated to
 6 the Trust Fund, out of any money in the Treasury not oth-
 7 erwise appropriated, an amount determined by the Sec-
 8 retary of the Treasury, in consultation with the Secretary
 9 of Health and Human Services, to be equal to the interest
 10 income lost by the Trust Fund through the date on which
 11 the appropriation is being made as a result of the clerical
 12 error.

13 **SEC. 624. SAFETY NET ORGANIZATIONS AND PATIENT ADVI-**
 14 **SORY COMMISSION.**

15 (a) *IN GENERAL.*—Title XI (42 U.S.C. 1320 *et seq.*)
 16 is amended by adding at the end the following new part:

17 “PART D—SAFETY NET ORGANIZATIONS AND PATIENT
 18 ADVISORY COMMISSION

19 “SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY
 20 COMMISSION

21 “SEC. 1181. (a) *ESTABLISHMENT.*—There is hereby es-
 22 tablished the Safety Net Organizations and Patient Advi-
 23 sory Commission (in this section referred to as the ‘Com-
 24 mission’).

1 “(b) *REVIEW OF HEALTH CARE SAFETY NET PRO-*
2 *GRAMS AND REPORTING REQUIREMENTS.*—

3 “(1) *REVIEW.*—*The Commission shall conduct*
4 *an ongoing review of the health care safety net pro-*
5 *grams (as described in paragraph (3)(C)) by—*

6 “(A) *monitoring each health care safety net*
7 *program to document and analyze the effects of*
8 *changes in these programs on the core health care*
9 *safety net;*

10 “(B) *evaluating the impact of the Emer-*
11 *gency Medical Treatment and Labor Act, the*
12 *Health Insurance Portability and Accountability*
13 *Act of 1996, the Balanced Budget Act of 1997,*
14 *the Medicare, Medicaid, and SCHIP Balanced*
15 *Budget Refinement Act of 1999, the Medicare,*
16 *Medicaid, and SCHIP Benefits Protection and*
17 *Improvement Act of 2000, Prescription Drug*
18 *and Medicare Improvement Act of 2003, and*
19 *other forces on the capacity of the core health*
20 *care safety net to continue their roles in the core*
21 *health care safety net system to care for unin-*
22 *insured individuals, medicaid beneficiaries, and*
23 *other vulnerable populations;*

1 “(C) monitoring existing data sets to assess
2 the status of the core health care safety net and
3 health outcomes for vulnerable populations;

4 “(D) wherever possible, linking and inte-
5 grating existing data systems to enhance the
6 ability of the core health care safety net to track
7 changes in the status of the core health care safe-
8 ty net and health outcomes for vulnerable popu-
9 lations;

10 “(E) supporting the development of new
11 data systems where existing data are insufficient
12 or inadequate;

13 “(F) developing criteria and indicators of
14 impending core health care safety net failure;

15 “(G) establishing an early-warning system
16 to identify impending failures of core health care
17 safety net systems and providers;

18 “(H) providing accurate and timely infor-
19 mation to Federal, State, and local policymakers
20 on the indicators that may lead to the failure of
21 the core health care safety net and an estimate
22 of the projected consequences of such failures and
23 the impact of such a failure on the community;

24 “(I) monitoring and providing oversight for
25 the transition of individuals receiving supple-

1 *mental security income benefits, medical assist-*
 2 *ance under title XIX, or child health assistance*
 3 *under title XXI who enroll with a managed care*
 4 *entity (as defined in section 1932(a)(1)(B)), in-*
 5 *cluding the review of—*

6 *“(i) the degree to which health plans*
 7 *have the capacity (including case manage-*
 8 *ment and management information system*
 9 *infrastructure) to provide quality managed*
 10 *care services to such an individual;*

11 *“(ii) the degree to which these plans*
 12 *may be overburdened by adverse selection;*
 13 *and*

14 *“(iii) the degree to which emergency*
 15 *departments are used by enrollees of these*
 16 *plans; and*

17 *“(J) identifying and disseminating the best*
 18 *practices for more effective application of the les-*
 19 *sons that have been learned.*

20 *“(2) REPORTS.—*

21 *“(A) ANNUAL REPORTS.—Not later than*
 22 *June 1 of each year (beginning with 2005), the*
 23 *Commission shall, based on the review conducted*
 24 *under paragraph (1), submit to the appropriate*
 25 *committees of Congress a report on—*

1 “(i) *the health care needs of the unin-*
2 *sured; and*

3 “(ii) *the financial and infrastructure*
4 *stability of the Nation’s core health care*
5 *safety net.*

6 “(B) *AGENDA AND ADDITIONAL REVIEWS.—*

7 “(i) *AGENDA.—The Chair of the Com-*
8 *mission shall consult periodically with the*
9 *Chairpersons and Ranking Minority Mem-*
10 *bers of the appropriate committees of Con-*
11 *gress regarding the Commission’s agenda*
12 *and progress toward achieving the agenda.*

13 “(ii) *ADDITIONAL REVIEWS.—The*
14 *Commission shall conduct additional re-*
15 *views and submit additional reports to the*
16 *appropriate committees of Congress on top-*
17 *ics relating to the health care safety net pro-*
18 *grams under the following circumstances:*

19 “(I) *If requested by the Chair-*
20 *persons or Ranking Minority Members*
21 *of such committees.*

22 “(II) *If the Commission deems*
23 *such additional reviews and reports*
24 *appropriate.*

1 “(C) *AVAILABILITY OF REPORTS.*—*The*
 2 *Commission shall transmit to the Comptroller*
 3 *General and the Secretary a copy of each report*
 4 *submitted under this subsection and shall make*
 5 *such reports available to the public.*

6 “(3) *DEFINITIONS.*—*In this section:*

7 “(A) *APPROPRIATE COMMITTEES OF CON-*
 8 *GRESS.*—*The term ‘appropriate committees of*
 9 *Congress’ means the Committees on Ways and*
 10 *Means and Energy and Commerce of the House*
 11 *of Representatives and the Committees on Fi-*
 12 *nance and Health, Education, Labor, and Pen-*
 13 *sions of the Senate.*

14 “(B) *CORE HEALTH CARE SAFETY NET.*—
 15 *The term ‘core health care safety net’ means any*
 16 *health care provider that—*

17 “(i) *by legal mandate or explicitly*
 18 *adopted mission, offers access to health care*
 19 *services to patients, regardless of the ability*
 20 *of the patient to pay for such services; and*

21 “(ii) *has a case mix that is substan-*
 22 *tially comprised of patients who are unin-*
 23 *sured, covered under the medicaid program,*
 24 *covered under any other public health care*

1 *program, or are otherwise vulnerable popu-*
 2 *lations.*

3 *Such term includes disproportionate share hos-*
 4 *pitals, Federally qualified health centers, other*
 5 *Federal, State, and locally supported clinics,*
 6 *rural health clinics, local health departments,*
 7 *and providers covered under the Emergency*
 8 *Medical Treatment and Labor Act.*

9 “(C) *HEALTH CARE SAFETY NET PRO-*
 10 *GRAMS.—The term ‘health care safety net pro-*
 11 *grams’ includes the following:*

12 “(i) *MEDICAID.—The medicaid pro-*
 13 *gram under title XIX.*

14 “(ii) *SCHIP.—The State children’s*
 15 *health insurance program under title XXI.*

16 “(iii) *MATERNAL AND CHILD HEALTH*
 17 *SERVICES BLOCK GRANT PROGRAM.—The*
 18 *maternal and child health services block*
 19 *grant program under title V.*

20 “(iv) *FQHC PROGRAMS.—Each feder-*
 21 *ally funded program under which a health*
 22 *center (as defined in section 330(1) of the*
 23 *Public Health Service Act), a Federally*
 24 *qualified health center (as defined in section*
 25 *1861(aa)(4)), or a Federally-qualified*

1 *health center (as defined in section*
 2 *1905(l)(2)(B)) receives funds.*

3 “(v) *RHC PROGRAMS.*—*Each federally*
 4 *funded program under which a rural health*
 5 *clinic (as defined in section 1861(aa)(4) or*
 6 *1905(l)(1)) receives funds.*

7 “(vi) *DSH PAYMENT PROGRAMS.*—
 8 *Each federally funded program under which*
 9 *a disproportionate share hospital receives*
 10 *funds.*

11 “(vii) *EMERGENCY MEDICAL TREAT-*
 12 *MENT AND ACTIVE LABOR ACT.*—*All care*
 13 *provided under section 1867 for the unin-*
 14 *sur ed, underinsured, beneficiaries under*
 15 *title XIX, and other vulnerable individuals.*

16 “(viii) *OTHER HEALTH CARE SAFETY*
 17 *NET PROGRAMS.*—*Such term also includes*
 18 *any other health care program that the*
 19 *Commission determines to be appropriate.*

20 “(D) *VULNERABLE POPULATIONS.*—*The*
 21 *term ‘vulnerable populations’ includes uninsured*
 22 *and underinsured individuals, low-income indi-*
 23 *viduals, farm workers, homeless individuals, in-*
 24 *dividuals with disabilities, individuals with HIV*

1 *or AIDS, and such other individuals as the Com-*
 2 *mission may designate.*

3 “(c) *MEMBERSHIP.*—

4 “(1) *NUMBER AND APPOINTMENT.*—*The Commis-*
 5 *sion shall be composed of 13 members appointed by*
 6 *the Comptroller General of the United States (in this*
 7 *section referred to as the ‘Comptroller General’), in*
 8 *consultation with the appropriate committees of Con-*
 9 *gress.*

10 “(2) *QUALIFICATIONS.*—

11 “(A) *IN GENERAL.*—*The membership of the*
 12 *Commission shall include individuals with na-*
 13 *tional recognition for their expertise in health fi-*
 14 *nance and economics, health care safety net re-*
 15 *search and program management, actuarial*
 16 *science, health facility management, health plans*
 17 *and integrated delivery systems, reimbursement*
 18 *of health facilities, allopathic and osteopathic*
 19 *medicine (including emergency medicine), and*
 20 *other providers of health services, and other re-*
 21 *lated fields, who provide a mix of different pro-*
 22 *fessionals, broad geographic representation, and*
 23 *a balance between urban and rural representa-*
 24 *tives.*

1 “(B) *INCLUSION.*—*The membership of the*
 2 *Commission shall include health professionals,*
 3 *employers, third-party payers, individuals*
 4 *skilled in the conduct and interpretation of bio-*
 5 *medical, health services, and health economics re-*
 6 *search and expertise in outcomes and effective-*
 7 *ness research and technology assessment. Such*
 8 *membership shall also include recipients of care*
 9 *from core health care safety net and individuals*
 10 *who provide and manage the delivery of care by*
 11 *the core health care safety net.*

12 “(C) *MAJORITY NONPROVIDERS.*—*Individ-*
 13 *uals who are directly involved in the provision,*
 14 *or management of the delivery, of items and*
 15 *services covered under the health care safety net*
 16 *programs shall not constitute a majority of the*
 17 *membership of the Commission.*

18 “(D) *ETHICAL DISCLOSURE.*—*The Comp-*
 19 *troller General shall establish a system for public*
 20 *disclosure by members of the Commission of fi-*
 21 *nancial and other potential conflicts of interest*
 22 *relating to such members.*

23 “(3) *TERMS.*—

24 “(A) *IN GENERAL.*—*The terms of members*
 25 *of the Commission shall be for 3 years except*

1 *that of the members first appointed, the Com-*
 2 *troller General shall designate—*

3 *“(i) four to serve a term of 1 year;*

4 *“(ii) four to serve a term of 2 years;*

5 *and*

6 *“(iii) five to serve a term of 3 years.*

7 *“(B) VACANCIES.—*

8 *“(i) IN GENERAL.—A vacancy in the*
 9 *Commission shall be filled in the same man-*
 10 *ner in which the original appointment was*
 11 *made.*

12 *“(ii) APPOINTMENT.—Any member ap-*
 13 *pointed to fill a vacancy occurring before*
 14 *the expiration of the term for which the*
 15 *member’s predecessor was appointed shall be*
 16 *appointed only for the remainder of that*
 17 *term.*

18 *“(iii) TERMS.—A member may serve*
 19 *after the expiration of that member’s term*
 20 *until a successor has taken office.*

21 *“(4) COMPENSATION.—*

22 *“(A) MEMBERS.—While serving on the busi-*
 23 *ness of the Commission (including travel time),*
 24 *a member of the Commission—*

1 “(i) shall be entitled to compensation
2 at the per diem equivalent of the rate pro-
3 vided for level IV of the Executive Schedule
4 under section 5315 of title 5, United States
5 Code; and

6 “(ii) while so serving away from home
7 and the member’s regular place of business,
8 may be allowed travel expenses, as author-
9 ized by the Commission.

10 “(B) TREATMENT.—For purposes of pay
11 (other than pay of members of the Commission)
12 and employment benefits, rights, and privileges,
13 all personnel of the Commission shall be treated
14 as if they were employees of the United States
15 Senate.

16 “(5) CHAIR; VICE CHAIR.—The Comptroller Gen-
17 eral shall designate a member of the Commission, at
18 the time of appointment of the member as Chair and
19 a member as Vice Chair for that term of appoint-
20 ment, except that in the case of vacancy of the Chair
21 or Vice Chair, the Comptroller General may designate
22 another member for the remainder of that member’s
23 term.

1 “(6) *MEETINGS.*—*The Commission shall meet at*
 2 *the call of the Chair or upon the written request of*
 3 *a majority of its members.*

4 “(d) *DIRECTOR AND STAFF; EXPERTS AND CONSULT-*
 5 *ANTS.*—*Subject to such review as the Comptroller General*
 6 *determines necessary to ensure the efficient administration*
 7 *of the Commission, the Commission may—*

8 “(1) *employ and fix the compensation of an Ex-*
 9 *ecutive Director (subject to the approval of the Comp-*
 10 *troller General) and such other personnel as may be*
 11 *necessary to carry out the duties of the Commission*
 12 *under this section (without regard to the provisions of*
 13 *title 5, United States Code, governing appointments*
 14 *in the competitive service);*

15 “(2) *seek such assistance and support as may be*
 16 *required in the performance of the duties of the Com-*
 17 *mission under this section from appropriate Federal*
 18 *departments and agencies;*

19 “(3) *enter into contracts or make other arrange-*
 20 *ments, as may be necessary for the conduct of the*
 21 *work of the Commission (without regard to section*
 22 *3709 of the Revised Statutes (41 U.S.C. 5));*

23 “(4) *make advance, progress, and other pay-*
 24 *ments which relate to the work of the Commission;*

1 “(5) *provide transportation and subsistence for*
 2 *persons serving without compensation; and*

3 “(6) *prescribe such rules and regulations as it*
 4 *deems necessary with respect to the internal organiza-*
 5 *tion and operation of the Commission.*

6 “(e) *POWERS.—*

7 “(1) *OBTAINING OFFICIAL DATA.—*

8 “(A) *IN GENERAL.—The Commission may*
 9 *secure directly from any department or agency of*
 10 *the United States information necessary for the*
 11 *Commission to carry the duties under this sec-*
 12 *tion.*

13 “(B) *REQUEST OF CHAIR.—Upon request of*
 14 *the Chair, the head of that department or agency*
 15 *shall furnish that information to the Commission*
 16 *on an agreed upon schedule.*

17 “(2) *DATA COLLECTION.—In order to carry out*
 18 *the duties of the Commission under this section, the*
 19 *Commission shall—*

20 “(A) *use existing information, both pub-*
 21 *lished and unpublished, where possible, collected*
 22 *and assessed either by the staff of the Commis-*
 23 *sion or under other arrangements made in ac-*
 24 *cordance with this section;*

1 “(B) carry out, or award grants or con-
 2 tracts for, original research and experimentation,
 3 where existing information is inadequate; and

4 “(C) adopt procedures allowing any inter-
 5 ested party to submit information for the Com-
 6 mission’s use in making reports and rec-
 7 ommendations.

8 “(3) ACCESS OF GAO TO INFORMATION.—The
 9 Comptroller General shall have unrestricted access to
 10 all deliberations, records, and nonproprietary data
 11 that pertains to the work of the Commission, imme-
 12 diately upon request. The expense of providing such
 13 information shall be borne by the General Accounting
 14 Office.

15 “(4) PERIODIC AUDIT.—The Commission shall be
 16 subject to periodic audit by the Comptroller General.

17 “(f) APPLICATION OF FACA.—Section 14 of the Fed-
 18 eral Advisory Committee Act (5 U.S.C. App.) does not
 19 apply to the Commission.

20 “(g) AUTHORIZATION OF APPROPRIATIONS.—

21 “(1) REQUEST FOR APPROPRIATIONS.—The
 22 Commission shall submit requests for appropriations
 23 in the same manner as the Comptroller General sub-
 24 mits requests for appropriations, but amounts appro-

1 *priated for the Commission shall be separate from*
 2 *amounts appropriated for the Comptroller General.*

3 *“(2) AUTHORIZATION.—There are authorized to*
 4 *be appropriated such sums as may be necessary to*
 5 *carry out the provisions of this section.”.*

6 *(b) EFFECTIVE DATE.—The Comptroller General of*
 7 *the United States shall appoint the initial members of the*
 8 *Safety Net Organizations and Patient Advisory Commis-*
 9 *sion established under subsection (a) not later than June*
 10 *1, 2004.*

11 **SEC. 625. URBAN HEALTH PROVIDER ADJUSTMENT.**

12 *(a) IN GENERAL.—Beginning with fiscal year 2004,*
 13 *notwithstanding section 1923(f) of the Social Security Act*
 14 *(42 U.S.C. 1396r–4(f)) and subject to subsection (c), with*
 15 *respect to a State, payment adjustments made under title*
 16 *XIX of the Social Security Act (42 U.S.C. 1396 et seq.)*
 17 *to a hospital described in subsection (b) shall be made with-*
 18 *out regard to the DSH allotment limitation for the State*
 19 *determined under section 1923(f) of that Act (42 U.S.C.*
 20 *1396r–4(f)).*

21 *(b) HOSPITAL DESCRIBED.—A hospital is described in*
 22 *this subsection if the hospital—*

23 *(1) is owned or operated by a State (as defined*
 24 *for purposes of title XIX of the Social Security Act),*
 25 *or by an instrumentality or a municipal govern-*

1 *mental unit within a State (as so defined) as of Jan-*
 2 *uary 1, 2003; and*

3 *(2) is located in Marion County, Indiana.*

4 *(c) LIMITATION.—The payment adjustment described*
 5 *in subsection (a) for fiscal year 2004 and each fiscal year*
 6 *thereafter shall not exceed 175 percent of the costs of fur-*
 7 *nishing hospital services described in section 1923(g)(1)(A)*
 8 *of the Social Security Act (42 U.S.C. 1396r–4(g)(1)(A)).*

9 **SEC. 626. COMMITTEE ON DRUG COMPOUNDING.**

10 *(a) ESTABLISHMENT.—The Secretary of Health and*
 11 *Human Services shall establish an Committee on Drug*
 12 *Compounding (referred to in this section as the “Com-*
 13 *mittee”)* *within the Food and Drug Administration on drug*
 14 *compounding to ensure that patients are receiving nec-*
 15 *essary, safe and accurate dosages of compounded drugs.*

16 *(b) MEMBERSHIP.—The membership of the Advisory*
 17 *Committee shall be appointed by the Secretary of Health*
 18 *and Human Services and shall include representatives of—*

19 *(1) the National Association of Boards of Phar-*
 20 *macy;*

21 *(2) pharmacy groups;*

22 *(3) physician groups;*

23 *(4) consumer and patient advocate groups;*

24 *(5) the United States Pharmacopoeia; and*

1 (6) *other individuals determined appropriate by*
 2 *the Secretary.*

3 (c) *REPORT AND RECOMMENDATIONS.—Not later than*
 4 *1 year after the date of enactment of this Act, the Committee*
 5 *shall submit to the Secretary a report concerning the rec-*
 6 *ommendations of the Committee to improve and protect pa-*
 7 *tient safety.*

8 (d) *TERMINATION.—The Committee shall terminate on*
 9 *the date that is 1 year after the date of enactment of this*
 10 *Act.*

11 **SEC. 627. SENSE OF THE SENATE CONCERNING THE STRUC-**
 12 **TURE OF MEDICARE REFORM AND THE PRE-**
 13 **SCRIPTION DRUG BENEFIT.**

14 (a) *FINDINGS.—The Senate makes the following find-*
 15 *ings:*

16 (1) *America’s seniors deserve a fiscally-strong*
 17 *medicare system that fulfills its promise to them and*
 18 *future retirees.*

19 (2) *The impending retirement of the “baby*
 20 *boom” generation will dramatically increase the costs*
 21 *of providing medicare benefits. Medicare costs will*
 22 *double relative to the size of the economy from 2 per-*
 23 *cent of GDP today to 4 percent in 2025 and double*
 24 *again to 8 percent of GDP in 2075. This growth will*

1 *accelerate substantially when Congress adds a nec-*
2 *essary prescription drug benefit.*

3 *(3) Medicare's current structure does not have*
4 *the flexibility to quickly adapt to rapid advances in*
5 *modern health care. Medicare lags far behind other*
6 *insurers in providing prescription drug coverage, dis-*
7 *ease management programs, and host of other ad-*
8 *vances. Reforming medicare to create a more self-ad-*
9 *justing, innovative structure is essential to improve*
10 *medicare's efficiency and the quality of the medical*
11 *care it provides.*

12 *(4) Private-sector choice for medicare bene-*
13 *ficiaries would provide two key benefits: It would be*
14 *tailored to the needs of America's seniors, not the*
15 *Government, and would create a powerful incentive*
16 *for private-sector medicare plans to provide the best*
17 *quality health care to seniors at the most affordable*
18 *price.*

19 *(5) The method by which the national preferred*
20 *provider organizations in the Federal Employees*
21 *Health Benefits Program have been reimbursed has*
22 *proven to be a reliable and successful mechanism for*
23 *providing Members of Congress and Federal employ-*
24 *ees with excellent health care choices.*

1 (6) *Unlike the medicare payment system, which*
 2 *has had to be changed by Congress every few years,*
 3 *the Federal Employees Health Benefits Program has*
 4 *existed for 43 years with minimal changes from Con-*
 5 *gress.*

6 (b) *SENSE OF THE SENATE.—It is the sense of the Sen-*
 7 *ate that medicare reform legislation should:*

8 (1) *Ensure that prescription drug coverage is di-*
 9 *rected to those who need it most.*

10 (2) *Provide that Government contributions used*
 11 *to support MedicareAdvantage plans are based on*
 12 *market principles beginning in 2006 to ensure the*
 13 *long- and short-term viability of such options for*
 14 *America's seniors.*

15 (3) *Develop a payment system for the*
 16 *MedicareAdvantage preferred provider organizations*
 17 *similar to the payment system used for the national*
 18 *preferred provider organizations in the Federal Em-*
 19 *ployees Health Benefits Program.*

20 (4) *Limit the addition of new unfunded obliga-*
 21 *tions in the medicare program so that the long-term*
 22 *solvency of this important program is not further*
 23 *jeopardized.*

1 (5) *Incorporate private sector, market-based ele-*
 2 *ments, that do not rely on the inefficient medicare*
 3 *price control structure.*

4 (6) *Keep the cost of structural changes and new*
 5 *benefits within the \$400,000,000,000 provided for*
 6 *under the current Congressional Budget Resolution*
 7 *for implementing medicare reform and providing a*
 8 *prescription drug benefit.*

9 (7) *Preserve the current employer-sponsored re-*
 10 *tiree health plans and not design a benefit which has*
 11 *the unintended consequences of supplanting private*
 12 *coverage.*

13 (8) *Incorporate regulatory reform proposals to*
 14 *eliminate red tape and reduce costs.*

15 (9) *Restore the right of medicare beneficiaries*
 16 *and their doctors to work together to provide services,*
 17 *allow private fee for service plans to set their own*
 18 *premiums, and permit seniors to add their own dol-*
 19 *lars beyond the Government contribution.*

20 **SEC. 628. SENSE OF THE SENATE REGARDING THE ESTAB-**
 21 **LISHMENT OF A NATIONWIDE PERMANENT**
 22 **LIFESTYLE MODIFICATION PROGRAM FOR**
 23 **MEDICARE BENEFICIARIES.**

24 (a) *FINDINGS.—Congress finds that:*

1 (1) *Heart disease kills more than 500,000 Ameri-*
2 *cans per year.*

3 (2) *The number and costs of interventions for the*
4 *treatment of coronary disease are rising and cur-*
5 *rently cost the health care system \$58,000,000,000 an-*
6 *nually.*

7 (3) *The Medicare Lifestyle Modification Program*
8 *has been operating throughout 12 States and has been*
9 *demonstrated to reduce the need for coronary proce-*
10 *dures by 88 percent per year.*

11 (4) *The Medicare Lifestyle Modification Program*
12 *is less expensive to deliver than interventional cardiac*
13 *procedures and could reduce cardiovascular expendi-*
14 *tures by \$36,000,000,000 annually.*

15 (5) *Lifestyle choices such as diet and exercise af-*
16 *fect heart disease and heart disease outcomes by 50*
17 *percent or greater.*

18 (6) *Intensive lifestyle interventions which include*
19 *teams of nurses, doctors, exercise physiologists, reg-*
20 *istered dietitians, and behavioral health clinicians*
21 *have been demonstrated to reduce heart disease risk*
22 *factors and enhance heart disease outcomes dramati-*
23 *cally.*

24 (7) *The National Institutes of Health estimates*
25 *that 17,000,000 Americans have diabetes and the Cen-*

1 *ters for Disease Control and Prevention estimates that*
 2 *the number of Americans who have a diagnosis of di-*
 3 *abetes increased 61 percent in the last decade and is*
 4 *expected to more than double by 2050.*

5 *(8) Lifestyle modification programs are superior*
 6 *to medication therapy for treating diabetes.*

7 *(9) Individuals with diabetes are now considered*
 8 *to have coronary disease at the date of diagnosis of*
 9 *their diabetic state.*

10 *(10) The Medicare Lifestyle Modification Pro-*
 11 *gram has been an effective lifestyle program for the*
 12 *reversal and treatment of heart disease.*

13 *(11) Men with prostate cancer have shown sig-*
 14 *nificant improvement in prostate cancer markers*
 15 *using a similar approach in lifestyle modification.*

16 *(12) These lifestyle changes are therefore likely to*
 17 *affect other chronic disease states, in addition to heart*
 18 *disease.*

19 *(b) SENSE OF THE SENATE.—It is the sense of the Sen-*
 20 *ate that—*

21 *(1) the Secretary of Health and Human Services*
 22 *should carry out the demonstration project known as*
 23 *the Lifestyle Modification Program Demonstration, as*
 24 *described in the Health Care Financing Administra-*

1 *tion Memorandum of Understanding entered into on*
 2 *November 13, 2000, on a permanent basis;*

3 *(2) the project should include as many Medicare*
 4 *beneficiaries as would like to participate in the*
 5 *project on a voluntary basis; and*

6 *(3) the project should be conducted on a national*
 7 *basis.*

8 **SEC. 629. SENSE OF THE SENATE ON PAYMENT REDUC-**
 9 **TIONS UNDER MEDICARE PHYSICIAN FEE**
 10 **SCHEDULE.**

11 *(a) FINDINGS.—Congress finds that—*

12 *(1) the fees medicare pays physicians were re-*
 13 *duced by 5.4 percent across-the-board in 2002;*

14 *(2) recent action by Congress narrowly averted*
 15 *another across-the-board reduction of 4.4 percent for*
 16 *2003;*

17 *(3) based on current projections, the Centers for*
 18 *Medicare & Medicaid Services (CMS) estimates that,*
 19 *absent legislative or administrative action, fees will be*
 20 *reduced across-the-board once again in 2004 by 4.2*
 21 *percent;*

22 *(4) the prospect of continued payment reductions*
 23 *under the medicare physician fee schedule for the fore-*
 24 *seeable future threatens to destabilize an important*

1 *element of the program, namely physician participa-*
2 *tion and willingness to accept medicare patients;*

3 *(5) the primary source of this instability is the*
4 *sustainable growth rate (SGR), a system of annual*
5 *spending targets for physicians' services under medi-*
6 *care;*

7 *(6) the SGR system has a number of defects that*
8 *result in unrealistically low spending targets, such as*
9 *the use of the increase in the gross domestic product*
10 *(GDP) as a proxy for increases in the volume and in-*
11 *tensity of services provided by physicians, no toler-*
12 *ance for variance between growth in medicare bene-*
13 *ficiary health care costs and our Nation's GDP, and*
14 *a requirement for immediate recoupment of the dif-*
15 *ference;*

16 *(7) both administrative and legislative action*
17 *are needed to return stability to the physician pay-*
18 *ment system;*

19 *(8) using the discretion given to it by medicare*
20 *law, CMS has included expenditures for prescription*
21 *drugs and biologicals administered incident to physi-*
22 *cians' services under the annual spending targets*
23 *without making appropriate adjustments to the tar-*
24 *gets to reflect price increases in these drugs and*

1 *biologicals or the growing reliance on such therapies*
 2 *in the treatment of medicare patients;*

3 *(9) between 1996 and 2002, annual medicare*
 4 *spending on these drugs grew from \$1,800,000,000 to*
 5 *\$6,200,000,000, or from \$55 per beneficiary to an es-*
 6 *timated \$187 per beneficiary;*

7 *(10) although physicians are responsible for pre-*
 8 *scribing these drugs and biologicals, neither the price*
 9 *of the drugs and biologicals, nor the standards of care*
 10 *that encourage their use, are within the control of*
 11 *physicians; and*

12 *(11) SGR target adjustments have not been made*
 13 *for cost increases due to new coverage decisions and*
 14 *new rules and regulations.*

15 *(b) SENSE OF THE SENATE.—It is the sense of the Sen-*
 16 *ate that—*

17 *(1) the Center for Medicare & Medicaid Services*
 18 *(CMS) should use its discretion to exclude drugs and*
 19 *biologicals administered incident to physician services*
 20 *from the sustainable growth rate (SGR) system;*

21 *(2) CMS should use its discretion to make SGR*
 22 *target adjustments for new coverage decisions and*
 23 *new rules and regulations; and*

24 *(3) in order to provide ample time for Congress*
 25 *to consider more fundamental changes to the SGR*

1 *system, the conferees on the Prescription Drug and*
 2 *Medicare Improvement Act of 2003 should include in*
 3 *the conference agreement a provision to establish a*
 4 *minimum percentage update in physician fees for the*
 5 *next 2 years and should consider adding provisions*
 6 *that would mitigate the swings in payment, such as*
 7 *establishing multi-year adjustments to recoup the*
 8 *variance and creating “tolerance” corridors for vari-*
 9 *ations around the update target trend.*

10 **SEC. 630. TEMPORARY SUSPENSION OF OASIS REQUIRE-**
 11 **MENT FOR COLLECTION OF DATA ON NON-**
 12 **MEDICARE AND NON-MEDICAID PATIENTS.**

13 *(a) IN GENERAL.—During the period described in sub-*
 14 *section (b), the Secretary may not require, under section*
 15 *4602(e) of the Balanced Budget Act of 1997 or otherwise*
 16 *under OASIS, a home health agency to gather or submit*
 17 *information that relates to an individual who is not eligible*
 18 *for benefits under either title XVIII or title XIX of the So-*
 19 *cial Security Act (such information in this section referred*
 20 *to as “non-medicare/medicaid OASIS information”).*

21 *(b) PERIOD OF SUSPENSION.—The period described in*
 22 *this subsection—*

23 *(1) begins on the date of the enactment of this*
 24 *Act; and*

1 (2) *ends on the last day of the 2nd month begin-*
2 *ning after the date as of which the Secretary has pub-*
3 *lished final regulations regarding the collection and*
4 *use by the Centers for Medicare & Medicaid Services*
5 *of non-medicare/medicaid OASIS information fol-*
6 *lowing the submission of the report required under*
7 *subsection (c).*

8 *(c) REPORT.—*

9 (1) *STUDY.—The Secretary shall conduct a study*
10 *on how non-medicare/medicaid OASIS information is*
11 *and can be used by large home health agencies. Such*
12 *study shall examine—*

13 (A) *whether there are unique benefits from*
14 *the analysis of such information that cannot be*
15 *derived from other information available to, or*
16 *collected by, such agencies; and*

17 (B) *the value of collecting such information*
18 *by small home health agencies compared to the*
19 *administrative burden related to such collection.*

20 *In conducting the study the Secretary shall obtain*
21 *recommendations from quality assessment experts in*
22 *the use of such information and the necessity of small,*
23 *as well as large, home health agencies collecting such*
24 *information.*

1 (2) *REPORT.*—*The Secretary shall submit to*
 2 *Congress a report on the study conducted under para-*
 3 *graph (1) by not later than 18 months after the date*
 4 *of the enactment of this Act.*

5 (d) *CONSTRUCTION.*—*Nothing in this section shall be*
 6 *construed as preventing home health agencies from col-*
 7 *lecting non-medicare/medicaid OASIS information for*
 8 *their own use.*

9 **SEC. 631. EMPLOYER FLEXIBILITY.**

10 (a) *MEDICARE.*—*Nothing in part D of title XVIII of*
 11 *the Social Security Act, as added by section 101, shall be*
 12 *construed as—*

13 (1) *preventing employment-based retiree health*
 14 *coverage (as defined in section 1860D–20(e)(4)(B) of*
 15 *such Act, as so added) from providing coverage that*
 16 *is supplemental to the benefits provided under a*
 17 *Medicare Prescription Drug plan under such part or*
 18 *a MedicareAdvantage plan under part C of such title,*
 19 *as amended by this Act; or*

20 (2) *requiring employment-based retiree health*
 21 *coverage (as so defined) that provides medical benefits*
 22 *to retired participants who are not eligible for med-*
 23 *ical benefits under title XVIII of the Social Security*
 24 *Act or under a plan maintained by a State or an*
 25 *agency thereof to provide medical benefits, or the*

1 *same medical benefits, to retired participants who are*
 2 *so eligible.*

3 **(b) ADEA.—**

4 **(1) IN GENERAL.—***Section 4(l) of the Age Dis-*
 5 *crimination in Employment Act of 1967 (29 U.S.C.*
 6 *623(l)) is amended by adding at the end the fol-*
 7 *lowing:*

8 *“(4) An employee benefit plan (as defined in sec-*
 9 *tion 3(3) of the Employee Retirement Income Secu-*
 10 *urity Act of 1974 (29 U.S.C. 1002(3))) shall not be*
 11 *treated as violating subsection (a), (b), (c), or (e) sole-*
 12 *ly because the plan provides medical benefits to re-*
 13 *tired participants who are not eligible for medical*
 14 *benefits under title XVIII of the Social Security Act*
 15 *(42 U.S.C. 1395 et seq.) or under a plan maintained*
 16 *by a State or an agency thereof, but does not provide*
 17 *medical benefits, or the same medical benefits, to re-*
 18 *tired participants who are so eligible.”*

19 **(2) EFFECTIVE DATE.—***The amendment made by*
 20 *this subsection shall apply as of the date of the enact-*
 21 *ment of this Act.*

1 **SEC. 632. ONE HUNDRED PERCENT FMAP FOR MEDICAL AS-**
 2 **SISTANCE PROVIDED TO A NATIVE HAWAIIAN**
 3 **THROUGH A FEDERALLY-QUALIFIED HEALTH**
 4 **CENTER OR A NATIVE HAWAIIAN HEALTH**
 5 **CARE SYSTEM UNDER THE MEDICAID PRO-**
 6 **GRAM.**

7 (a) *MEDICAID.*—Section 1905(b) of the Social Security
 8 Act (42 U.S.C. 1396d(b)) is amended, in the third sentence,
 9 by inserting “, and with respect to medical assistance pro-
 10 vided to a Native Hawaiian (as defined in section 12 of
 11 the Native Hawaiian Health Care Improvement Act)
 12 through a federally-qualified health center or a Native Ha-
 13 waiian health care system (as so defined) whether directly,
 14 by referral, or under contract or other arrangement between
 15 a federally-qualified health center or a Native Hawaiian
 16 health care system and another health care provider” before
 17 the period.

18 (b) *EFFECTIVE DATE.*—The amendment made by this
 19 section applies to medical assistance provided on or after
 20 the date of enactment of this Act.

21 **SEC. 633. EXTENSION OF MORATORIUM.**

22 (a) *IN GENERAL.*—Section 6408(a)(3) of the Omnibus
 23 Budget Reconciliation Act of 1989, as amended by section
 24 13642 of the Omnibus Budget Reconciliation Act of 1993
 25 and section 4758 of the Balanced Budget Act of 1997, is
 26 amended—

1 (1) *by striking “until December 31, 2002”, and*

2 (2) *by striking “Kent Community Hospital*
3 *Complex in Michigan or.”*

4 **(b) EFFECTIVE DATES.—**

5 (1) **PERMANENT EXTENSION.**—*The amendment*
6 *made by subsection (a)(1) shall take effect as if in-*
7 *cluded in the amendment made by section 4758 of the*
8 *Balanced Budget Act of 1997.*

9 (2) **MODIFICATION.**—*The amendment made by*
10 *subsection (a)(2) shall take effect on the date of enact-*
11 *ment of this Act.*

12 **SEC. 634. GAO STUDY OF PHARMACEUTICAL PRICE CON-**
13 **TROLS AND PATENT PROTECTIONS IN THE G-**
14 **7 COUNTRIES.**

15 (a) **STUDY.**—*The Comptroller General of the United*
16 *States shall conduct a study of price controls imposed on*
17 *pharmaceuticals in France, Germany, Italy, Japan, the*
18 *United Kingdom and Canada to review the impact such*
19 *regulations have on consumers, including American con-*
20 *sumers, and on innovation in medicine. The study shall in-*
21 *clude the following:*

22 (1) *The pharmaceutical price control structure*
23 *in each country for a wide range of pharmaceuticals,*
24 *compared with average pharmaceutical prices paid by*
25 *Americans covered by private sector health insurance.*

1 (2) *The proportion of the cost for innovation*
 2 *borne by American consumers, compared with con-*
 3 *sumers in the other 6 countries.*

4 (3) *A review of how closely the observed prices in*
 5 *regulated markets correspond to the prices that effi-*
 6 *ciently distribute common costs of production*
 7 *(“Ramsey prices”).*

8 (4) *A review of any peer-reviewed literature that*
 9 *might show the health consequences to patients in the*
 10 *listed countries that result from the absence or de-*
 11 *layed introduction of medicines, including the cost of*
 12 *not having access to medicines, in terms of lower life*
 13 *expectancy and lower quality of health.*

14 (5) *The impact on American consumers, in*
 15 *terms of reduced research into new or improved phar-*
 16 *maceuticals (including the cost of delaying the intro-*
 17 *duction of a significant advance in certain major dis-*
 18 *eases), if similar price controls were adopted in the*
 19 *United States.*

20 (6) *The existing standards under international*
 21 *conventions, including the World Trade Organization*
 22 *and the North American Free Trade Agreement, re-*
 23 *garding regulated pharmaceutical prices, including*
 24 *any restrictions on anti-competitive laws that might*
 25 *apply to price regulations and how economic harm*

1 *caused to consumers in markets without price regula-*
 2 *tions may be remedied.*

3 *(7) In parallel trade regimes, how much of the*
 4 *price difference between countries in the European*
 5 *Union is captured by middlemen and how much goes*
 6 *to benefit patients and health systems where parallel*
 7 *importing is significant.*

8 *(8) How much cost is imposed on the owner of*
 9 *a property right from counterfeiting and from inter-*
 10 *national violations of intellectual property rights for*
 11 *prescription medicines.*

12 *(b) REPORT.—Not later than 1 year after the date of*
 13 *enactment of this Act, the Comptroller General of the United*
 14 *States shall submit to Congress a report on the study con-*
 15 *ducted under subsection (a).*

16 **SEC. 635. SAFETY NET ORGANIZATIONS AND PATIENT ADVI-**
 17 **SORY COMMISSION.**

18 *(a) IN GENERAL.—Title XI (42 U.S.C. 1320 et seq.)*
 19 *is amended by adding at the end the following new part:*

20 **“PART D—SAFETY NET ORGANIZATIONS AND PATIENT**
 21 **ADVISORY COMMISSION**

22 **“SAFETY NET ORGANIZATIONS AND PATIENT ADVISORY**
 23 **COMMISSION**

24 **“SEC. 1181. (a) ESTABLISHMENT.—There is hereby es-**
 25 **tablished the Safety Net Organizations and Patient Advi-**

1 sory Commission (in this section referred to as the ‘Com-
2 mission’).

3 “(b) *REVIEW OF HEALTH CARE SAFETY NET PRO-*
4 *GRAMS AND REPORTING REQUIREMENTS.*—

5 “(1) *REVIEW.*—*The Commission shall conduct*
6 *an ongoing review of the health care safety net pro-*
7 *grams (as described in paragraph (3)(C)) by—*

8 “(A) *monitoring each health care safety net*
9 *program to document and analyze the effects of*
10 *changes in these programs on the core health care*
11 *safety net;*

12 “(B) *evaluating the impact of the Emer-*
13 *gency Medical Treatment and Labor Act, the*
14 *Health Insurance Portability and Accountability*
15 *Act of 1996, the Balanced Budget Act of 1997,*
16 *the Medicare, Medicaid, and SCHIP Balanced*
17 *Budget Refinement Act of 1999, the Medicare,*
18 *Medicaid, and SCHIP Benefits Protection and*
19 *Improvement Act of 2000, Prescription Drug*
20 *and Medicare Improvement Act of 2003, and*
21 *other forces on the capacity of the core health*
22 *care safety net to continue their roles in the core*
23 *health care safety net system to care for unin-*
24 *sured individuals, medicaid beneficiaries, and*
25 *other vulnerable populations;*

1 “(C) monitoring existing data sets to assess
2 the status of the core health care safety net and
3 health outcomes for vulnerable populations;

4 “(D) wherever possible, linking and inte-
5 grating existing data systems to enhance the
6 ability of the core health care safety net to track
7 changes in the status of the core health care safe-
8 ty net and health outcomes for vulnerable popu-
9 lations;

10 “(E) supporting the development of new
11 data systems where existing data are insufficient
12 or inadequate;

13 “(F) developing criteria and indicators of
14 impending core health care safety net failure;

15 “(G) establishing an early-warning system
16 to identify impending failures of core health care
17 safety net systems and providers;

18 “(H) providing accurate and timely infor-
19 mation to Federal, State, and local policymakers
20 on the indicators that may lead to the failure of
21 the core health care safety net and an estimate
22 of the projected consequences of such failures and
23 the impact of such a failure on the community;

24 “(I) monitoring and providing oversight for
25 the transition of individuals receiving supple-

1 *mental security income benefits, medical assist-*
 2 *ance under title XIX, or child health assistance*
 3 *under title XXI who enroll with a managed care*
 4 *entity (as defined in section 1932(a)(1)(B)), in-*
 5 *cluding the review of—*

6 *“(i) the degree to which health plans*
 7 *have the capacity (including case manage-*
 8 *ment and management information system*
 9 *infrastructure) to provide quality managed*
 10 *care services to such an individual;*

11 *“(ii) the degree to which these plans*
 12 *may be overburdened by adverse selection;*
 13 *and*

14 *“(iii) the degree to which emergency*
 15 *departments are used by enrollees of these*
 16 *plans; and*

17 *“(J) identifying and disseminating the best*
 18 *practices for more effective application of the les-*
 19 *sons that have been learned.*

20 *“(2) REPORTS.—*

21 *“(A) ANNUAL REPORTS.—Not later than*
 22 *June 1 of each year (beginning with 2005), the*
 23 *Commission shall, based on the review conducted*
 24 *under paragraph (1), submit to the appropriate*
 25 *committees of Congress a report on—*

1 “(i) *the health care needs of the unin-*
2 *sured; and*

3 “(ii) *the financial and infrastructure*
4 *stability of the Nation’s core health care*
5 *safety net.*

6 “(B) *AGENDA AND ADDITIONAL REVIEWS.—*

7 “(i) *AGENDA.—The Chair of the Com-*
8 *mission shall consult periodically with the*
9 *Chairpersons and Ranking Minority Mem-*
10 *bers of the appropriate committees of Con-*
11 *gress regarding the Commission’s agenda*
12 *and progress toward achieving the agenda.*

13 “(ii) *ADDITIONAL REVIEWS.—The*
14 *Commission shall conduct additional re-*
15 *views and submit additional reports to the*
16 *appropriate committees of Congress on top-*
17 *ics relating to the health care safety net pro-*
18 *grams under the following circumstances:*

19 “(I) *If requested by the Chair-*
20 *persons or Ranking Minority Members*
21 *of such committees.*

22 “(II) *If the Commission deems*
23 *such additional reviews and reports*
24 *appropriate.*

1 “(C) *AVAILABILITY OF REPORTS.*—*The*
 2 *Commission shall transmit to the Comptroller*
 3 *General and the Secretary a copy of each report*
 4 *submitted under this subsection and shall make*
 5 *such reports available to the public.*

6 “(3) *DEFINITIONS.*—*In this section:*

7 “(A) *APPROPRIATE COMMITTEES OF CON-*
 8 *GRESS.*—*The term ‘appropriate committees of*
 9 *Congress’ means the Committees on Ways and*
 10 *Means and Energy and Commerce of the House*
 11 *of Representatives and the Committees on Fi-*
 12 *nance and Health, Education, Labor, and Pen-*
 13 *sions of the Senate.*

14 “(B) *CORE HEALTH CARE SAFETY NET.*—
 15 *The term ‘core health care safety net’ means any*
 16 *health care provider that—*

17 “(i) *by legal mandate or explicitly*
 18 *adopted mission, offers access to health care*
 19 *services to patients, regardless of the ability*
 20 *of the patient to pay for such services; and*

21 “(ii) *has a case mix that is substan-*
 22 *tially comprised of patients who are unin-*
 23 *sured, covered under the medicaid program,*
 24 *covered under any other public health care*

1 *program, or are otherwise vulnerable popu-*
 2 *lations.*

3 *Such term includes disproportionate share hos-*
 4 *pitals, Federally qualified health centers, other*
 5 *Federal, State, and locally supported clinics,*
 6 *rural health clinics, local health departments,*
 7 *and providers covered under the Emergency*
 8 *Medical Treatment and Labor Act.*

9 “(C) *HEALTH CARE SAFETY NET PRO-*
 10 *GRAMS.—The term ‘health care safety net pro-*
 11 *grams’ includes the following:*

12 “(i) *MEDICAID.—The medicaid pro-*
 13 *gram under title XIX.*

14 “(ii) *SCHIP.—The State children’s*
 15 *health insurance program under title XXI.*

16 “(iii) *MATERNAL AND CHILD HEALTH*
 17 *SERVICES BLOCK GRANT PROGRAM.—The*
 18 *maternal and child health services block*
 19 *grant program under title V.*

20 “(iv) *FQHC PROGRAMS.—Each feder-*
 21 *ally funded program under which a health*
 22 *center (as defined in section 330(1) of the*
 23 *Public Health Service Act), a Federally*
 24 *qualified health center (as defined in section*
 25 *1861(aa)(4)), or a Federally-qualified*

1 *health center (as defined in section*
 2 *1905(l)(2)(B)) receives funds.*

3 “(v) *RHC PROGRAMS.*—*Each federally*
 4 *funded program under which a rural health*
 5 *clinic (as defined in section 1861(aa)(4) or*
 6 *1905(l)(1)) receives funds.*

7 “(vi) *DSH PAYMENT PROGRAMS.*—
 8 *Each federally funded program under which*
 9 *a disproportionate share hospital receives*
 10 *funds.*

11 “(vii) *EMERGENCY MEDICAL TREAT-*
 12 *MENT AND ACTIVE LABOR ACT.*—*All care*
 13 *provided under section 1867 for the unin-*
 14 *sur ed, underinsured, beneficiaries under*
 15 *title XIX, and other vulnerable individuals.*

16 “(viii) *OTHER HEALTH CARE SAFETY*
 17 *NET PROGRAMS.*—*Such term also includes*
 18 *any other health care program that the*
 19 *Commission determines to be appropriate.*

20 “(D) *VULNERABLE POPULATIONS.*—*The*
 21 *term ‘vulnerable populations’ includes uninsured*
 22 *and underinsured individuals, low-income indi-*
 23 *viduals, farm workers, homeless individuals, in-*
 24 *dividuals with disabilities, individuals with HIV*

1 *or AIDS, and such other individuals as the Com-*
 2 *mission may designate.*

3 “(c) *MEMBERSHIP.*—

4 “(1) *NUMBER AND APPOINTMENT.*—*The Commis-*
 5 *sion shall be composed of 13 members appointed by*
 6 *the Comptroller General of the United States (in this*
 7 *section referred to as the ‘Comptroller General’), in*
 8 *consultation with the appropriate committees of Con-*
 9 *gress.*

10 “(2) *QUALIFICATIONS.*—

11 “(A) *IN GENERAL.*—*The membership of the*
 12 *Commission shall include individuals with na-*
 13 *tional recognition for their expertise in health fi-*
 14 *nance and economics, health care safety net re-*
 15 *search and program management, actuarial*
 16 *science, health facility management, health plans*
 17 *and integrated delivery systems, reimbursement*
 18 *of health facilities, allopathic and osteopathic*
 19 *medicine (including emergency medicine), and*
 20 *other providers of health services, and other re-*
 21 *lated fields, who provide a mix of different pro-*
 22 *fessionals, broad geographic representation, and*
 23 *a balance between urban and rural representa-*
 24 *tives.*

1 “(B) *INCLUSION.*—*The membership of the*
2 *Commission shall include health professionals,*
3 *employers, third-party payers, individuals*
4 *skilled in the conduct and interpretation of bio-*
5 *medical, health services, and health economics re-*
6 *search and expertise in outcomes and effective-*
7 *ness research and technology assessment. Such*
8 *membership shall also include recipients of care*
9 *from core health care safety net and individuals*
10 *who provide and manage the delivery of care by*
11 *the core health care safety net.*

12 “(C) *MAJORITY NONPROVIDERS.*—*Individ-*
13 *uals who are directly involved in the provision,*
14 *or management of the delivery, of items and*
15 *services covered under the health care safety net*
16 *programs shall not constitute a majority of the*
17 *membership of the Commission.*

18 “(D) *ETHICAL DISCLOSURE.*—*The Comp-*
19 *troller General shall establish a system for public*
20 *disclosure by members of the Commission of fi-*
21 *nancial and other potential conflicts of interest*
22 *relating to such members.*

23 “(3) *TERMS.*—

24 “(A) *IN GENERAL.*—*The terms of members*
25 *of the Commission shall be for 3 years except*

1 *that of the members first appointed, the Comp-*
 2 *troller General shall designate—*

3 *“(i) four to serve a term of 1 year;*

4 *“(ii) four to serve a term of 2 years;*

5 *and*

6 *“(iii) five to serve a term of 3 years.*

7 *“(B) VACANCIES.—*

8 *“(i) IN GENERAL.—A vacancy in the*
 9 *Commission shall be filled in the same man-*
 10 *ner in which the original appointment was*
 11 *made.*

12 *“(ii) APPOINTMENT.—Any member ap-*
 13 *pointed to fill a vacancy occurring before*
 14 *the expiration of the term for which the*
 15 *member’s predecessor was appointed shall be*
 16 *appointed only for the remainder of that*
 17 *term.*

18 *“(iii) TERMS.—A member may serve*
 19 *after the expiration of that member’s term*
 20 *until a successor has taken office.*

21 *“(4) COMPENSATION.—*

22 *“(A) MEMBERS.—While serving on the busi-*
 23 *ness of the Commission (including travel time),*
 24 *a member of the Commission—*

1 “(i) shall be entitled to compensation
2 at the per diem equivalent of the rate pro-
3 vided for level IV of the Executive Schedule
4 under section 5315 of title 5, United States
5 Code; and

6 “(ii) while so serving away from home
7 and the member’s regular place of business,
8 may be allowed travel expenses, as author-
9 ized by the Commission.

10 “(B) TREATMENT.—For purposes of pay
11 (other than pay of members of the Commission)
12 and employment benefits, rights, and privileges,
13 all personnel of the Commission shall be treated
14 as if they were employees of the United States
15 Senate.

16 “(5) CHAIR; VICE CHAIR.—The Comptroller Gen-
17 eral shall designate a member of the Commission, at
18 the time of appointment of the member as Chair and
19 a member as Vice Chair for that term of appoint-
20 ment, except that in the case of vacancy of the Chair
21 or Vice Chair, the Comptroller General may designate
22 another member for the remainder of that member’s
23 term.

1 “(6) *MEETINGS.*—*The Commission shall meet at*
2 *the call of the Chair or upon the written request of*
3 *a majority of its members.*

4 “(d) *DIRECTOR AND STAFF; EXPERTS AND CONSULT-*
5 *ANTS.*—*Subject to such review as the Comptroller General*
6 *determines necessary to ensure the efficient administration*
7 *of the Commission, the Commission may—*

8 “(1) *employ and fix the compensation of an Ex-*
9 *ecutive Director (subject to the approval of the Comp-*
10 *troller General) and such other personnel as may be*
11 *necessary to carry out the duties of the Commission*
12 *under this section (without regard to the provisions of*
13 *title 5, United States Code, governing appointments*
14 *in the competitive service);*

15 “(2) *seek such assistance and support as may be*
16 *required in the performance of the duties of the Com-*
17 *mission under this section from appropriate Federal*
18 *departments and agencies;*

19 “(3) *enter into contracts or make other arrange-*
20 *ments, as may be necessary for the conduct of the*
21 *work of the Commission (without regard to section*
22 *3709 of the Revised Statutes (41 U.S.C. 5));*

23 “(4) *make advance, progress, and other pay-*
24 *ments which relate to the work of the Commission;*

1 “(5) *provide transportation and subsistence for*
 2 *persons serving without compensation; and*

3 “(6) *prescribe such rules and regulations as it*
 4 *deems necessary with respect to the internal organiza-*
 5 *tion and operation of the Commission.*

6 “(e) *POWERS.—*

7 “(1) *OBTAINING OFFICIAL DATA.—*

8 “(A) *IN GENERAL.—The Commission may*
 9 *secure directly from any department or agency of*
 10 *the United States information necessary for the*
 11 *Commission to carry the duties under this sec-*
 12 *tion.*

13 “(B) *REQUEST OF CHAIR.—Upon request of*
 14 *the Chair, the head of that department or agency*
 15 *shall furnish that information to the Commission*
 16 *on an agreed upon schedule.*

17 “(2) *DATA COLLECTION.—In order to carry out*
 18 *the duties of the Commission under this section, the*
 19 *Commission shall—*

20 “(A) *use existing information, both pub-*
 21 *lished and unpublished, where possible, collected*
 22 *and assessed either by the staff of the Commis-*
 23 *sion or under other arrangements made in ac-*
 24 *cordance with this section;*

1 “(B) carry out, or award grants or con-
 2 tracts for, original research and experimentation,
 3 where existing information is inadequate; and

4 “(C) adopt procedures allowing any inter-
 5 ested party to submit information for the Com-
 6 mission’s use in making reports and rec-
 7 ommendations.

8 “(3) ACCESS OF GAO TO INFORMATION.—The
 9 Comptroller General shall have unrestricted access to
 10 all deliberations, records, and nonproprietary data
 11 that pertains to the work of the Commission, imme-
 12 diately upon request. The expense of providing such
 13 information shall be borne by the General Accounting
 14 Office.

15 “(4) PERIODIC AUDIT.—The Commission shall be
 16 subject to periodic audit by the Comptroller General.

17 “(f) APPLICATION OF FACA.—Section 14 of the Fed-
 18 eral Advisory Committee Act (5 U.S.C. App.) does not
 19 apply to the Commission.

20 “(g) AUTHORIZATION OF APPROPRIATIONS.—

21 “(1) REQUEST FOR APPROPRIATIONS.—The
 22 Commission shall submit requests for appropriations
 23 in the same manner as the Comptroller General sub-
 24 mits requests for appropriations, but amounts appro-

1 *priated for the Commission shall be separate from*
 2 *amounts appropriated for the Comptroller General.*

3 *“(2) AUTHORIZATION.—There are authorized to*
 4 *be appropriated such sums as may be necessary to*
 5 *carry out the provisions of this section.”.*

6 *(b) EFFECTIVE DATE.—The Comptroller General of*
 7 *the United States shall appoint the initial members of the*
 8 *Safety Net Organizations and Patient Advisory Commis-*
 9 *sion established under subsection (a) not later than June*
 10 *1, 2004.*

11 **SEC. 636. ESTABLISHMENT OF PROGRAM TO PREVENT**
 12 **ABUSE OF NURSING FACILITY RESIDENTS.**

13 *(a) IN GENERAL.—*

14 *(1) SCREENING OF SKILLED NURSING FACILITY*
 15 *AND NURSING FACILITY PROVISIONAL EMPLOYEES.—*

16 *(A) MEDICARE PROGRAM.—Section 1819(b)*
 17 *(42 U.S.C. 1395i–3(b)) is amended by adding at*
 18 *the end the following:*

19 *“(8) SCREENING OF SKILLED NURSING FACILITY*
 20 *WORKERS.—*

21 *“(A) BACKGROUND CHECKS OF PROVI-*
 22 *SIONAL EMPLOYEES.—Subject to subparagraph*
 23 *(B)(ii), after a skilled nursing facility selects an*
 24 *individual for a position as a skilled nursing fa-*
 25 *cility worker, the facility, prior to employing*

1 *such worker in a status other than a provisional*
2 *status to the extent permitted under subpara-*
3 *graph (B)(ii), shall—*

4 *“(i) give such worker written notice*
5 *that the facility is required to perform back-*
6 *ground checks with respect to provisional*
7 *employees;*

8 *“(ii) require, as a condition of employ-*
9 *ment, that such worker—*

10 *“(I) provide a written statement*
11 *disclosing any conviction for a relevant*
12 *crime or finding of patient or resident*
13 *abuse;*

14 *“(II) provide a statement signed*
15 *by the worker authorizing the facility*
16 *to request the search and exchange of*
17 *criminal records;*

18 *“(III) provide in person to the fa-*
19 *cility a copy of the worker’s finger-*
20 *prints or thumb print, depending upon*
21 *available technology; and*

22 *“(IV) provide any other identi-*
23 *fication information the Secretary may*
24 *specify in regulation;*

1 “(iii) initiate a check of the data col-
2 lection system established under section
3 1128E in accordance with regulations pro-
4 mulgated by the Secretary to determine
5 whether such system contains any disquali-
6 fying information with respect to such
7 worker; and

8 “(iv) if that system does not contain
9 any such disqualifying information—

10 “(I) request through the appro-
11 priate State agency that the State ini-
12 tiate a State and national criminal
13 background check on such worker in
14 accordance with the provisions of sub-
15 section (e)(6); and

16 “(II) submit to such State agency
17 the information described in subclauses
18 (II) through (IV) of clause (ii) not
19 more than 7 days (excluding Satur-
20 days, Sundays, and legal public holi-
21 days under section 6103(a) of title 5,
22 United States Code) after completion of
23 the check against the system initiated
24 under clause (iii).

1 “(B) *PROHIBITION ON HIRING OF ABUSIVE*
2 *WORKERS.*—

3 “(i) *IN GENERAL.*—*A skilled nursing*
4 *facility may not knowingly employ any*
5 *skilled nursing facility worker who has any*
6 *conviction for a relevant crime or with re-*
7 *spect to whom a finding of patient or resi-*
8 *dent abuse has been made.*

9 “(ii) *PROVISIONAL EMPLOYMENT.*—
10 *After complying with the requirements of*
11 *clauses (i), (ii), and (iii) of subparagraph*
12 *(A), a skilled nursing facility may provide*
13 *for a provisional period of employment for*
14 *a skilled nursing facility worker pending*
15 *completion of the check against the data col-*
16 *lection system described under subpara-*
17 *graph (A)(iii) and the background check de-*
18 *scribed under subparagraph (A)(iv). Subject*
19 *to clause (iii), such facility shall maintain*
20 *direct supervision of the covered individual*
21 *during the worker’s provisional period of*
22 *employment.*

23 “(iii) *EXCEPTION FOR SMALL RURAL*
24 *SKILLED NURSING FACILITIES.*—*In the case*
25 *of a small rural skilled nursing facility (as*

defined by the Secretary), the Secretary shall provide, by regulation after consultation with providers of skilled nursing facility services and entities representing beneficiaries of such services, for an appropriate level of supervision with respect to any provisional employees employed by the facility in accordance with clause (ii). Such regulation should encourage the provision of direct supervision of such employees whenever practicable with respect to such a facility and if such supervision would not impose an unreasonable cost or other burden on the facility.

“(C) *REPORTING REQUIREMENTS.*—A skilled nursing facility shall report to the State any instance in which the facility determines that a skilled nursing facility worker has committed an act of resident neglect or abuse or misappropriation of resident property in the course of employment by the facility.

“(D) *USE OF INFORMATION.*—

“(i) *IN GENERAL.*—A skilled nursing facility that obtains information about a skilled nursing facility worker pursuant to

1 *clauses (iii) and (iv) of subparagraph (A)*
 2 *may use such information only for the pur-*
 3 *pose of determining the suitability of the*
 4 *worker for employment.*

5 “(ii) *IMMUNITY FROM LIABILITY.*—A
 6 *skilled nursing facility that, in denying em-*
 7 *ployment for an individual selected for hir-*
 8 *ing as a skilled nursing facility worker (in-*
 9 *cluding during the period described in sub-*
 10 *paragraph (B)(ii)), reasonably relies upon*
 11 *information about such individual provided*
 12 *by the State pursuant to subsection (e)(6) or*
 13 *section 1128E shall not be liable in any ac-*
 14 *tion brought by such individual based on*
 15 *the employment determination resulting*
 16 *from the information.*

17 “(iii) *CRIMINAL PENALTY.*—Whoever
 18 *knowingly violates the provisions of clause*
 19 *(i) shall be fined in accordance with title*
 20 *18, United States Code, imprisoned for not*
 21 *more than 2 years, or both.*

22 “(E) *CIVIL PENALTY.*—

23 “(i) *IN GENERAL.*—A skilled nursing
 24 *facility that violates the provisions of this*

paragraph shall be subject to a civil penalty
in an amount not to exceed—

“(I) for the first such violation,
\$2,000; and

“(II) for the second and each sub-
sequent violation within any 5-year
period, \$5,000.

“(ii) *KNOWING RETENTION OF WORK-
ER.*—In addition to any civil penalty
under clause (i), a skilled nursing facility
that—

“(I) knowingly continues to em-
ploy a skilled nursing facility worker
in violation of subparagraph (A) or
(B); or

“(II) knowingly fails to report a
skilled nursing facility worker under
subparagraph (C),

shall be subject to a civil penalty in an
amount not to exceed \$5,000 for the first
such violation, and \$10,000 for the second
and each subsequent violation within any 5-
year period.

“(F) *DEFINITIONS.*—In this paragraph:

1 “(i) *CONVICTION FOR A RELEVANT*
 2 *CRIME.*—*The term ‘conviction for a relevant*
 3 *crime’ means any Federal or State criminal*
 4 *conviction for—*

5 “(I) *any offense described in*
 6 *paragraphs (1) through (4) of section*
 7 *1128(a); and*

8 “(II) *such other types of offenses*
 9 *as the Secretary may specify in regula-*
 10 *tions, taking into account the severity*
 11 *and relevance of such offenses, and*
 12 *after consultation with representatives*
 13 *of long-term care providers, representa-*
 14 *tives of long-term care employees, con-*
 15 *sumer advocates, and appropriate Fed-*
 16 *eral and State officials.*

17 “(ii) *DISQUALIFYING INFORMATION.*—
 18 *The term ‘disqualifying information’ means*
 19 *information about a conviction for a rel-*
 20 *evant crime or a finding of patient or resi-*
 21 *dent abuse.*

22 “(iii) *FINDING OF PATIENT OR RESI-*
 23 *DENT ABUSE.*—*The term ‘finding of patient*
 24 *or resident abuse’ means any substantiated*
 25 *finding by a State agency under subsection*

1 (g)(1)(C) or a Federal agency that a skilled
2 nursing facility worker has committed—

3 “(I) an act of patient or resident
4 abuse or neglect or a misappropriation
5 of patient or resident property; or

6 “(II) such other types of acts as
7 the Secretary may specify in regula-
8 tions.

9 “(iv) *SKILLED NURSING FACILITY*
10 *WORKER.*—The term ‘skilled nursing facil-
11 ity worker’ means any individual (other
12 than a volunteer) that has access to a pa-
13 tient of a skilled nursing facility under an
14 employment or other contract, or both, with
15 such facility. Such term includes individ-
16 uals who are licensed or certified by the
17 State to provide such services, and non-
18 licensed individuals providing such services,
19 as defined by the Secretary, including nurse
20 assistants, nurse aides, home health aides,
21 and personal care workers and attendants.”.

22 (B) *MEDICAID PROGRAM.*—Section 1919(b)
23 (42 U.S.C. 1396r(b)) is amended by adding at
24 the end the following new paragraph:

1 “(8) *SCREENING OF NURSING FACILITY WORK-*
2 *ERS.—*

3 “(A) *BACKGROUND CHECKS ON PROVI-*
4 *SIONAL EMPLOYEES.—Subject to subparagraph*
5 *(B)(ii), after a nursing facility selects an indi-*
6 *vidual for a position as a nursing facility work-*
7 *er, the facility, prior to employing such worker*
8 *in a status other than a provisional status to the*
9 *extent permitted under subparagraph (B)(ii),*
10 *shall—*

11 “(i) *give the worker written notice that*
12 *the facility is required to perform back-*
13 *ground checks with respect to provisional*
14 *employees;*

15 “(ii) *require, as a condition of employ-*
16 *ment, that such worker—*

17 “(I) *provide a written statement*
18 *disclosing any conviction for a relevant*
19 *crime or finding of patient or resident*
20 *abuse;*

21 “(II) *provide a statement signed*
22 *by the worker authorizing the facility*
23 *to request the search and exchange of*
24 *criminal records;*

1 “(III) provide in person to the fa-
 2 cility a copy of the worker’s finger-
 3 prints or thumb print, depending upon
 4 available technology; and

5 “(IV) provide any other identi-
 6 fication information the Secretary may
 7 specify in regulation;

8 “(iii) initiate a check of the data col-
 9 lection system established under section
 10 1128E in accordance with regulations pro-
 11 mulgated by the Secretary to determine
 12 whether such system contains any disquali-
 13 fying information with respect to such
 14 worker; and

15 “(iv) if that system does not contain
 16 any such disqualifying information—

17 “(I) request through the appro-
 18 priate State agency that the State ini-
 19 tiate a State and national criminal
 20 background check on such worker in
 21 accordance with the provisions of sub-
 22 section (e)(8); and

23 “(II) submit to such State agency
 24 the information described in subclauses
 25 (II) through (IV) of clause (ii) not

more than 7 days (excluding Saturdays, Sundays, and legal public holidays under section 6103(a) of title 5, United States Code) after completion of the check against the system initiated under clause (iii).

“(B) *PROHIBITION ON HIRING OF ABUSIVE WORKERS.*—

“(i) *IN GENERAL.*—A nursing facility may not knowingly employ any nursing facility worker who has any conviction for a relevant crime or with respect to whom a finding of patient or resident abuse has been made.

“(ii) *PROVISIONAL EMPLOYMENT.*—After complying with the requirements of clauses (i), (ii), and (iii) of subparagraph (A), a nursing facility may provide for a provisional period of employment for a nursing facility worker pending completion of the check against the data collection system described under subparagraph (A)(iii) and the background check described under subparagraph (A)(iv). Subject to clause (iii), such facility shall maintain direct su-

1 *pervision of the worker during the worker's*
2 *provisional period of employment.*

3 “(iii) *EXCEPTION FOR SMALL RURAL*
4 *NURSING FACILITIES.*—

5 “(I) *IN GENERAL.*—*In the case of*
6 *a small rural nursing facility (as de-*
7 *finied by the Secretary), the Secretary*
8 *shall provide, by regulation after con-*
9 *sultation with providers of nursing fa-*
10 *cility services and entities representing*
11 *beneficiaries of such services, for an*
12 *appropriate level of supervision with*
13 *respect to any provisional employees*
14 *employed by the facility in accordance*
15 *with clause (ii). Such regulation*
16 *should encourage the provision of di-*
17 *rect supervision of such employees*
18 *whenever practicable with respect to*
19 *such a facility and if such supervision*
20 *would not impose an unreasonable cost*
21 *or other burden on the facility.*

22 “(C) *REPORTING REQUIREMENTS.*—*A nurs-*
23 *ing facility shall report to the State any instance*
24 *in which the facility determines that a nursing*
25 *facility worker has committed an act of resident*

neglect or abuse or misappropriation of resident property in the course of employment by the facility.

“(D) *USE OF INFORMATION.*—

“(i) *IN GENERAL.*—A nursing facility that obtains information about a nursing facility worker pursuant to clauses (iii) and (iv) of subparagraph (A) may use such information only for the purpose of determining the suitability of the worker for employment.

“(ii) *IMMUNITY FROM LIABILITY.*—A nursing facility that, in denying employment for an individual selected for hiring as a nursing facility worker (including during the period described in subparagraph (B)(ii)), reasonably relies upon information about such individual provided by the State pursuant to subsection (e)(6) or section 1128E shall not be liable in any action brought by such individual based on the employment determination resulting from the information.

“(iii) *CRIMINAL PENALTY.*—Whoever knowingly violates the provisions of clause

1 *(i) shall be fined in accordance with title*
 2 *18, United States Code, imprisoned for not*
 3 *more than 2 years, or both.*

4 “(E) CIVIL PENALTY.—

5 “(i) IN GENERAL.—A nursing facility
 6 *that violates the provisions of this para-*
 7 *graph shall be subject to a civil penalty in*
 8 *an amount not to exceed—*

9 “(I) for the first such violation,
 10 \$2,000; and

11 “(II) for the second and each sub-
 12 sequent violation within any 5-year
 13 period, \$5,000.

14 “(ii) KNOWING RETENTION OF WORK-
 15 *ER.—In addition to any civil penalty*
 16 *under clause (i), a nursing facility that—*

17 “(I) knowingly continues to em-
 18 ploy a nursing facility worker in vio-
 19 lation of subparagraph (A) or (B); or

20 “(II) knowingly fails to report a
 21 nursing facility worker under subpara-
 22 graph (C),

23 *shall be subject to a civil penalty in an*
 24 *amount not to exceed \$5,000 for the first*
 25 *such violation, and \$10,000 for the second*

1 *and each subsequent violation within any 5-*
 2 *year period.*

3 “(F) *DEFINITIONS.—In this paragraph:*

4 “*(i) CONVICTION FOR A RELEVANT*
 5 *CRIME.—The term ‘conviction for a relevant*
 6 *crime’ means any Federal or State criminal*
 7 *conviction for—*

8 “*(I) any offense described in*
 9 *paragraphs (1) through (4) of section*
 10 *1128(a); and*

11 “*(II) such other types of offenses*
 12 *as the Secretary may specify in regula-*
 13 *tions, taking into account the severity*
 14 *and relevance of such offenses, and*
 15 *after consultation with representatives*
 16 *of long-term care providers, representa-*
 17 *tives of long-term care employees, con-*
 18 *sumer advocates, and appropriate Fed-*
 19 *eral and State officials.*

20 “*(ii) DISQUALIFYING INFORMATION.—*
 21 *The term ‘disqualifying information’ means*
 22 *information about a conviction for a rel-*
 23 *evant crime or a finding of patient or resi-*
 24 *dent abuse.*

1 “(iii) *FINDING OF PATIENT OR RESI-*
 2 *DENT ABUSE.*—*The term ‘finding of patient*
 3 *or resident abuse’ means any substantiated*
 4 *finding by a State agency under subsection*
 5 *(g)(1)(C) or a Federal agency that a nurs-*
 6 *ing facility worker has committed—*

7 “(I) *an act of patient or resident*
 8 *abuse or neglect or a misappropriation*
 9 *of patient or resident property; or*

10 “(II) *such other types of acts as*
 11 *the Secretary may specify in regula-*
 12 *tions.*

13 “(iv) *NURSING FACILITY WORKER.*—
 14 *The term ‘nursing facility worker’ means*
 15 *any individual (other than a volunteer)*
 16 *that has access to a patient of a nursing fa-*
 17 *cility under an employment or other con-*
 18 *tract, or both, with such facility. Such term*
 19 *includes individuals who are licensed or*
 20 *certified by the State to provide such serv-*
 21 *ices, and nonlicensed individuals providing*
 22 *such services, as defined by the Secretary,*
 23 *including nurse assistants, nurse aides,*
 24 *home health aides, and personal care work-*
 25 *ers and attendants.”.*

1 (2) *FEDERAL RESPONSIBILITIES.*—

2 (A) *DEVELOPMENT OF STANDARD FEDERAL*
3 *AND STATE BACKGROUND CHECK FORM.*—*The*
4 *Secretary of Health and Human Services, in*
5 *consultation with the Attorney General and rep-*
6 *resentatives of appropriate State agencies, shall*
7 *develop a model form that a provisional em-*
8 *ployee at a nursing facility may complete and*
9 *Federal and State agencies may use to conduct*
10 *the criminal background checks required under*
11 *sections 1819(b)(8) and 1919(b)(8) of the Social*
12 *Security Act (42 U.S.C. 1395i–3(b), 1396r(b))*
13 *(as added by this section).*

14 (B) *PERIODIC EVALUATION.*—*The Secretary*
15 *of Health and Human Services, in consultation*
16 *with the Attorney General, periodically shall*
17 *evaluate the background check system imposed*
18 *under sections 1819(b)(8) and 1919(b)(8) of the*
19 *Social Security Act (42 U.S.C. 1395i–3(b),*
20 *1396r(b)) (as added by this section) and shall*
21 *implement changes, as necessary, based on avail-*
22 *able technology, to make the background check*
23 *system more efficient and able to provide a more*
24 *immediate response to long-term care providers*
25 *using the system.*

1 (3) NO PREEMPTION OF STRICTER STATE
 2 LAWS.—*Nothing in section 1819(b)(8) or 1919(b)(8)*
 3 *of the Social Security Act (42 U.S.C. 1395i–3(b)(8),*
 4 *1396r(b)(8)) (as so added) shall be construed to super-*
 5 *sede any provision of State law that—*

6 (A) *specifies a relevant crime for purposes*
 7 *of prohibiting the employment of an individual*
 8 *at a long-term care facility (as defined in section*
 9 *1128E(g)(6) of the Social Security Act (as added*
 10 *by subsection (e)) that is not included in the list*
 11 *of such crimes specified in such sections or in*
 12 *regulations promulgated by the Secretary of*
 13 *Health and Human Services to carry out such*
 14 *sections; or*

15 (B) *requires a long-term care facility (as so*
 16 *defined) to conduct a background check prior to*
 17 *employing an individual in an employment po-*
 18 *sition that is not included in the positions for*
 19 *which a background check is required under such*
 20 *sections.*

21 (4) TECHNICAL AMENDMENTS.—*Effective as if*
 22 *included in the enactment of section 941 of BIPA*
 23 *(114 Stat. 2763A–585), sections 1819(b) and 1919(b)*
 24 *(42 U.S.C. 1395i–3(b), 1396r(b)), as amended by such*
 25 *section 941 are each amended by redesignating the*

1 *paragraph (8) added by such section as paragraph*
 2 *(9).*

3 ***(b) FEDERAL AND STATE REQUIREMENTS CON-***
 4 ***CERNING BACKGROUND CHECKS.—***

5 ***(1) MEDICARE.—Section 1819(e) (42 U.S.C.***
 6 ***1395i–3(e)) is amended by adding at the end the fol-***
 7 ***lowing:***

8 ***“(6) FEDERAL AND STATE REQUIREMENTS CON-***
 9 ***CERNING CRIMINAL BACKGROUND CHECKS ON***
 10 ***SKILLED NURSING FACILITY EMPLOYEES.—***

11 ***“(A) IN GENERAL.—Upon receipt of a re-***
 12 ***quest by a skilled nursing facility pursuant to***
 13 ***subsection (b)(8) that is accompanied by the in-***
 14 ***formation described in subclauses (II) through***
 15 ***(IV) of subsection (b)(8)(A)(ii), a State, after***
 16 ***checking appropriate State records and finding***
 17 ***no disqualifying information (as defined in sub-***
 18 ***section (b)(8)(F)(ii)), shall immediately submit***
 19 ***such request and information to the Attorney***
 20 ***General and shall request the Attorney General***
 21 ***to conduct a search and exchange of records with***
 22 ***respect to the individual as described in sub-***
 23 ***paragraph (B).***

24 ***“(B) SEARCH AND EXCHANGE OF RECORDS***
 25 ***BY ATTORNEY GENERAL.—Upon receipt of a sub-***

mission pursuant to subparagraph (A), the Attorney General shall direct a search of the records of the Federal Bureau of Investigation for any criminal history records corresponding to the fingerprints and other positive identification information submitted. The Attorney General shall provide any corresponding information resulting from the search to the State.

“(C) STATE REPORTING OF INFORMATION TO SKILLED NURSING FACILITY.—Upon receipt of the information provided by the Attorney General pursuant to subparagraph (B), the State shall—

“(i) review the information to determine whether the individual has any conviction for a relevant crime (as defined in subsection (b)(8)(F)(i));

“(ii) immediately report to the skilled nursing facility in writing the results of such review; and

“(iii) in the case of an individual with a conviction for a relevant crime, report the existence of such conviction of such individual to the database established under section 1128E.

1 “(D) *FEEES FOR PERFORMANCE OF CRIMI-*
 2 *NAL BACKGROUND CHECKS.—*

3 “(i) *AUTHORITY TO CHARGE FEES.—*

4 “(I) *ATTORNEY GENERAL.—The*
 5 *Attorney General may charge a fee to*
 6 *any State requesting a search and ex-*
 7 *change of records pursuant to this*
 8 *paragraph and subsection (b)(8) for*
 9 *conducting the search and providing*
 10 *the records. The amount of such fee*
 11 *shall not exceed the lesser of the actual*
 12 *cost of such activities or \$50. Such fees*
 13 *shall be available to the Attorney Gen-*
 14 *eral, or, in the Attorney General’s dis-*
 15 *cretion, to the Federal Bureau of Inves-*
 16 *tigation until expended.*

17 “(II) *STATE.—A State may*
 18 *charge a skilled nursing facility a fee*
 19 *for initiating the criminal background*
 20 *check under this paragraph and sub-*
 21 *section (b)(8), including fees charged*
 22 *by the Attorney General, and for per-*
 23 *forming the review and report required*
 24 *by subparagraph (C). The amount of*

1 *such fee shall not exceed the actual cost*
 2 *of such activities.*

3 “(ii) *PROHIBITION ON CHARGING.*—An
 4 *entity may not impose on a provisional em-*
 5 *ployee or an employee any charges relating*
 6 *to the performance of a background check*
 7 *under this paragraph.*

8 “(E) *REGULATIONS.*—

9 “(i) *IN GENERAL.*—In addition to the
 10 *Secretary’s authority to promulgate regula-*
 11 *tions under this title, the Attorney General,*
 12 *in consultation with the Secretary, may*
 13 *promulgate such regulations as are nec-*
 14 *essary to carry out the Attorney General’s*
 15 *responsibilities under this paragraph and*
 16 *subsection (b)(9), including regulations re-*
 17 *garding the security confidentiality, accu-*
 18 *racy, use, destruction, and dissemination of*
 19 *information, audits and recordkeeping, and*
 20 *the imposition of fees.*

21 “(ii) *APPEAL PROCEDURES.*—The At-
 22 *torney General, in consultation with the*
 23 *Secretary, shall promulgate such regulations*
 24 *as are necessary to establish procedures by*
 25 *which a provisional employee or an em-*

1 *ployee may appeal or dispute the accuracy*
 2 *of the information obtained in a back-*
 3 *ground check conducted under this para-*
 4 *graph. Appeals shall be limited to instances*
 5 *in which a provisional employee or an em-*
 6 *ployee is incorrectly identified as the subject*
 7 *of the background check, or when informa-*
 8 *tion about the provisional employee or em-*
 9 *ployee has not been updated to reflect*
 10 *changes in the provisional employee's or*
 11 *employee's criminal record.*

12 “(F) *REPORT.*—Not later than 2 years after
 13 *the date of enactment of this paragraph, the At-*
 14 *torney General shall submit a report to Congress*
 15 *on—*

16 “(i) *the number of requests for searches*
 17 *and exchanges of records made under this*
 18 *section;*

19 “(ii) *the disposition of such requests;*
 20 *and*

21 “(iii) *the cost of responding to such re-*
 22 *quests.”.*

23 (2) *MEDICAID.*—Section 1919(e) (42 U.S.C.
 24 1396r(e)) *is amended by adding at the end the fol-*
 25 *lowing:*

1 “(8) *FEDERAL AND STATE REQUIREMENTS CON-*
 2 *CERNING CRIMINAL BACKGROUND CHECKS ON NURS-*
 3 *ING FACILITY EMPLOYEES.*—

4 “(A) *IN GENERAL.*—Upon receipt of a re-
 5 quest by a nursing facility pursuant to sub-
 6 section (b)(8) that is accompanied by the infor-
 7 mation described in subclauses (II) through (IV)
 8 of subsection (b)(8)(A)(ii), a State, after checking
 9 appropriate State records and finding no dis-
 10 qualifying information (as defined in subsection
 11 (b)(8)(F)(ii)), shall immediately submit such re-
 12 quest and information to the Attorney General
 13 and shall request the Attorney General to con-
 14 duct a search and exchange of records with re-
 15 spect to the individual as described in subpara-
 16 graph (B).

17 “(B) *SEARCH AND EXCHANGE OF RECORDS*
 18 *BY ATTORNEY GENERAL.*—Upon receipt of a sub-
 19 mission pursuant to subparagraph (A), the At-
 20 torney General shall direct a search of the
 21 records of the Federal Bureau of Investigation
 22 for any criminal history records corresponding
 23 to the fingerprints and other positive identifica-
 24 tion information submitted. The Attorney Gen-

1 *eral shall provide any corresponding information*
 2 *resulting from the search to the State.*

3 “(C) *STATE REPORTING OF INFORMATION*
 4 *TO NURSING FACILITY.*—Upon receipt of the in-
 5 *formation provided by the Attorney General pur-*
 6 *suant to subparagraph (B), the State shall—*

7 “(i) *review the information to deter-*
 8 *mine whether the individual has any con-*
 9 *viction for a relevant crime (as defined in*
 10 *subsection (b)(8)(F)(i));*

11 “(ii) *immediately report to the nursing*
 12 *facility in writing the results of such re-*
 13 *view; and*

14 “(iii) *in the case of an individual with*
 15 *a conviction for a relevant crime, report the*
 16 *existence of such conviction of such indi-*
 17 *vidual to the database established under sec-*
 18 *tion 1128E.*

19 “(D) *FEES FOR PERFORMANCE OF CRIMI-*
 20 *NAL BACKGROUND CHECKS.*—

21 “(i) *AUTHORITY TO CHARGE FEES.*—

22 “(I) *ATTORNEY GENERAL.*—*The*
 23 *Attorney General may charge a fee to*
 24 *any State requesting a search and ex-*
 25 *change of records pursuant to this*

1 *paragraph and subsection (b)(8) for*
2 *conducting the search and providing*
3 *the records. The amount of such fee*
4 *shall not exceed the lesser of the actual*
5 *cost of such activities or \$50. Such fees*
6 *shall be available to the Attorney Gen-*
7 *eral, or, in the Attorney General's dis-*
8 *cretion, to the Federal Bureau of Inves-*
9 *tigation, until expended.*

10 “(II) *STATE.—A State may*
11 *charge a nursing facility a fee for ini-*
12 *tiating the criminal background check*
13 *under this paragraph and subsection*
14 *(b)(8), including fees charged by the*
15 *Attorney General, and for performing*
16 *the review and report required by sub-*
17 *paragraph (C). The amount of such fee*
18 *shall not exceed the actual cost of such*
19 *activities.*

20 “(ii) *PROHIBITION ON CHARGING.—An*
21 *entity may not impose on a provisional em-*
22 *ployee or an employee any charges relating*
23 *to the performance of a background check*
24 *under this paragraph.*

25 “(E) *REGULATIONS.—*

1 “(i) *IN GENERAL.*—*In addition to the*
2 *Secretary’s authority to promulgate regula-*
3 *tions under this title, the Attorney General,*
4 *in consultation with the Secretary, may*
5 *promulgate such regulations as are nec-*
6 *essary to carry out the Attorney General’s*
7 *responsibilities under this paragraph and*
8 *subsection (b)(8), including regulations re-*
9 *garding the security, confidentiality, accu-*
10 *racy, use, destruction, and dissemination of*
11 *information, audits and recordkeeping, and*
12 *the imposition of fees.*

13 “(ii) *APPEAL PROCEDURES.*—*The At-*
14 *torney General, in consultation with the*
15 *Secretary, shall promulgate such regulations*
16 *as are necessary to establish procedures by*
17 *which a provisional employee or an em-*
18 *ployee may appeal or dispute the accuracy*
19 *of the information obtained in a back-*
20 *ground check conducted under this para-*
21 *graph. Appeals shall be limited to instances*
22 *in which a provisional employee or an em-*
23 *ployee is incorrectly identified as the subject*
24 *of the background check, or when informa-*
25 *tion about the provisional employee or em-*

1 *ployee has not been updated to reflect*
 2 *changes in the provisional employee’s or*
 3 *employee’s criminal record.*

4 *“(F) REPORT.—Not later than 2 years after*
 5 *the date of enactment of this paragraph, the At-*
 6 *torney General shall submit a report to Congress*
 7 *on—*

8 *“(i) the number of requests for searches*
 9 *and exchanges of records made under this*
 10 *section;*

11 *“(ii) the disposition of such requests;*
 12 *and*

13 *“(iii) the cost of responding to such re-*
 14 *quests.”.*

15 *(c) APPLICATION TO OTHER ENTITIES PROVIDING*
 16 *HOME HEALTH OR LONG-TERM CARE SERVICES.—*

17 *(1) MEDICARE.—Part D of title XVIII (42*
 18 *U.S.C. 1395x et seq.) is amended by adding at the*
 19 *end the following:*

20 *“APPLICATION OF SKILLED NURSING FACILITY PREVENTIVE*
 21 *ABUSE PROVISIONS TO ANY PROVIDER OF SERVICES*
 22 *OR OTHER ENTITY PROVIDING HOME HEALTH OR*
 23 *LONG-TERM CARE SERVICES*

24 *“SEC. 1897. (a) IN GENERAL.—The requirements of*
 25 *subsections (b)(8) and (e)(6) of section 1819 shall apply to*
 26 *any provider of services or any other entity that is eligible*

1 *to be paid under this title for providing home health serv-*
 2 *ices, hospice care (including routine home care and other*
 3 *services included in hospice care under this title), or long-*
 4 *term care services to an individual entitled to benefits under*
 5 *part A or enrolled under part B, including an individual*
 6 *provided with a Medicare+Choice plan offered by a*
 7 *Medicare+Choice organization under part C (in this sec-*
 8 *tion referred to as a ‘medicare beneficiary’).*

9 “(b) *SUPERVISION OF PROVISIONAL EMPLOYEES.*—

10 “(1) *IN GENERAL.*—*With respect to an entity*
 11 *that provides home health services, such entity shall*
 12 *be considered to have satisfied the requirements of sec-*
 13 *tion 1819(b)(8)(B)(ii) or 1919(b)(8)(B)(ii) if the enti-*
 14 *ty meets such requirements for supervision of provi-*
 15 *sional employees of the entity as the Secretary shall,*
 16 *by regulation, specify in accordance with paragraph*
 17 *(2).*

18 “(2) *REQUIREMENTS.*—*The regulations required*
 19 *under paragraph (1) shall provide the following:*

20 “(A) *Supervision of a provisional employee*
 21 *shall consist of ongoing, good faith, verifiable ef-*
 22 *forts by the supervisor of the provisional em-*
 23 *ployee to conduct monitoring and oversight ac-*
 24 *tivities to ensure the safety of a medicare bene-*
 25 *ficiary.*

1 “(B) For purposes of subparagraph (A),
2 monitoring and oversight activities may include
3 (but are not limited to) the following:

4 “(i) Follow-up telephone calls to the
5 medicare beneficiary.

6 “(ii) Unannounced visits to the medi-
7 care beneficiary’s home while the provi-
8 sional employee is serving the medicare ben-
9 eficiary.

10 “(iii) To the extent practicable, lim-
11 iting the provisional employee’s duties to
12 serving only those medicare beneficiaries in
13 a home or setting where another family
14 member or resident of the home or setting of
15 the medicare beneficiary is present.

16 “(C) In promulgating such regulations, the
17 Secretary shall take into account the staffing and
18 geographic issues faced by small rural entities
19 (as defined by the Secretary) that provide home
20 health services, hospice care (including routine
21 home care and other services included in hospice
22 care under this title), or other long-term care
23 services. Such regulations should encourage the
24 provision of monitoring and oversight activities
25 whenever practicable with respect to such an en-

1 *tity, and if such activities would not impose an*
 2 *unreasonable cost or other burden on the enti-*
 3 *ty.”.*

4 (2) *MEDICAID.*—Section 1902(a) (42 U.S.C.
 5 1396a), as amended by section 104(a), is amended—

6 (A) in paragraph (65), by striking “and”
 7 at the end;

8 (B) in paragraph (66), by striking the pe-
 9 riod and inserting “; and”; and

10 (C) by inserting after paragraph (66) the
 11 following:

12 “(67) provide that any entity that is eligible to
 13 be paid under the State plan for providing home
 14 health services, hospice care (including routine home
 15 care and other services included in hospice care under
 16 title XVIII), or long-term care services for which med-
 17 ical assistance is available under the State plan to
 18 individuals requiring long-term care complies with
 19 the requirements of subsections (b)(8) and (e)(8) of
 20 section 1919 and section 1897(b) (in the same man-
 21 ner as such section applies to a medicare bene-
 22 ficiary).”.

23 (3) *EXPANSION OF STATE NURSE AIDE REG-*
 24 *ISTRY.*—

1 (A) *MEDICARE*.—Section 1819 (42 U.S.C.
2 1395i–3) is amended—

3 (i) in subsection (e)(2)—

4 (I) in the paragraph heading, by
5 striking “NURSE AIDE REGISTRY” and
6 inserting “EMPLOYEE REGISTRY”;

7 (II) in subparagraph (A)—

8 (aa) by striking “By not
9 later than January 1, 1989, the”
10 and inserting “The”;

11 (bb) by striking “a registry
12 of all individuals” and inserting
13 “a registry of (i) all individuals”;
14 and

15 (cc) by inserting before the
16 period the following: “, (ii) all
17 other skilled nursing facility em-
18 ployees with respect to whom the
19 State has made a finding de-
20 scribed in subparagraph (B), and
21 (iii) any employee of any pro-
22 vider of services or any other enti-
23 ty that is eligible to be paid under
24 this title for providing home
25 health services, hospice care (in-

1 *cluding routine home care and*
 2 *other services included in hospice*
 3 *care under this title), or long-term*
 4 *care services and with respect to*
 5 *whom the entity has reported to*
 6 *the State a finding of patient ne-*
 7 *glect or abuse or a misappropria-*
 8 *tion of patient property”; and*
 9 *(III) in subparagraph (C), by*
 10 *striking “a nurse aide” and inserting*
 11 *“an individual”; and*
 12 *(ii) in subsection (g)(1)—*

13 *(I) by striking the first sentence of*
 14 *subparagraph (C) and inserting the*
 15 *following: “The State shall provide,*
 16 *through the agency responsible for sur-*
 17 *veys and certification of skilled nurs-*
 18 *ing facilities under this subsection, for*
 19 *a process for the receipt and timely re-*
 20 *view and investigation of allegations of*
 21 *neglect and abuse and misappropria-*
 22 *tion of resident property by a nurse*
 23 *aide or a skilled nursing facility em-*
 24 *ployee of a resident in a skilled nurs-*
 25 *ing facility, by another individual*

1 *used by the facility in providing serv-*
 2 *ices to such a resident, or by an indi-*
 3 *vidual described in subsection*
 4 *(e)(2)(A)(iii).”; and*

5 *(II) in the fourth sentence of sub-*
 6 *paragraph (C), by inserting “or de-*
 7 *scribed in subsection (e)(2)(A)(iii)”*
 8 *after “used by the facility”; and*

9 *(III) in subparagraph (D)—*

10 *(aa) in the subparagraph*
 11 *heading, by striking “NURSE*
 12 *AIDE”; and*

13 *(bb) in clause (i), in the mat-*
 14 *ter preceding subclause (I), by*
 15 *striking “a nurse aide” and in-*
 16 *serting “an individual”; and*

17 *(cc) in clause (i)(I), by strik-*
 18 *ing “nurse aide” and inserting*
 19 *“individual”.*

20 *(B) MEDICAID.—Section 1919 (42 U.S.C.*
 21 *1396r) is amended—*

22 *(i) in subsection (e)(2)—*

23 *(I) in the paragraph heading, by*
 24 *striking “NURSE AIDE REGISTRY” and*
 25 *inserting “EMPLOYEE REGISTRY”;*

1 (II) in subparagraph (A)—

2 (aa) by striking “By not
3 later than January 1, 1989, the”
4 and inserting “The”;

5 (bb) by striking “a registry
6 of all individuals” and inserting
7 “a registry of (i) all individuals”;
8 and

9 (cc) by inserting before the
10 period the following: “, (ii) all
11 other nursing facility employees
12 with respect to whom the State
13 has made a finding described in
14 subparagraph (B), and (iii) any
15 employee of an entity that is eligi-
16 ble to be paid under the State
17 plan for providing home health
18 services, hospice care (including
19 routine home care and other serv-
20 ices included in hospice care
21 under title XVIII), or long-term
22 care services and with respect to
23 whom the entity has reported to
24 the State a finding of patient ne-

1 *glect or abuse or a misappropria-*
 2 *tion of patient property”; and*

3 (III) in subparagraph (C), by
 4 striking “a nurse aide” and inserting
 5 “an individual”; and
 6 (ii) in subsection (g)(1)—

7 (I) by striking the first sentence of
 8 subparagraph (C) and inserting the
 9 following: “The State shall provide,
 10 through the agency responsible for sur-
 11 veys and certification of nursing facili-
 12 ties under this subsection, for a process
 13 for the receipt and timely review and
 14 investigation of allegations of neglect
 15 and abuse and misappropriation of
 16 resident property by a nurse aide or a
 17 nursing facility employee of a resident
 18 in a nursing facility, by another indi-
 19 vidual used by the facility in pro-
 20 viding services to such a resident, or by
 21 an individual described in subsection
 22 (e)(2)(A)(iii).”; and

23 (II) in the fourth sentence of sub-
 24 paragraph (C), by inserting “or de-

1 scribed in subsection (e)(2)(A)(iii)”
 2 after “used by the facility”; and
 3 (III) in subparagraph (D)—
 4 (aa) in the subparagraph
 5 heading, by striking “NURSE
 6 AIDE”; and
 7 (bb) in clause (i), in the mat-
 8 ter preceding subclause (I), by
 9 striking “a nurse aide” and in-
 10 serting “an individual”; and
 11 (cc) in clause (i)(I), by strik-
 12 ing “nurse aide” and inserting
 13 “individual”.

14 (d) *REIMBURSEMENT OF COSTS FOR BACKGROUND*
 15 *CHECKS.*—*The Secretary of Health and Human Services*
 16 *shall reimburse nursing facilities, skilled nursing facilities,*
 17 *and other entities for costs incurred by the facilities and*
 18 *entities in order to comply with the requirements imposed*
 19 *under sections 1819(b)(8) and 1919(b)(8) of such Act (42*
 20 *U.S.C. 1395i–3(b)(8), 1396r(b)(8)), as added by this sec-*
 21 *tion.*

22 (e) *INCLUSION OF ABUSIVE ACTS WITHIN A LONG-*
 23 *TERM CARE FACILITY OR PROVIDER IN THE NATIONAL*
 24 *HEALTH CARE FRAUD AND ABUSE DATA COLLECTION*
 25 *PROGRAM.*—

1 (1) *IN GENERAL.*—Section 1128E(g)(1)(A) (42
2 U.S.C. 1320a–7e(g)(1)(A)) is amended—

3 (A) by redesignating clause (v) as clause
4 (vi); and

5 (B) by inserting after clause (iv), the fol-
6 lowing:

7 “(v) A finding of abuse or neglect of a
8 patient or a resident of a long-term care fa-
9 cility, or misappropriation of such a pa-
10 tient’s or resident’s property.”.

11 (2) *COVERAGE OF LONG-TERM CARE FACILITY OR*
12 *PROVIDER EMPLOYEES.*—Section 1128E(g)(2) (42
13 U.S.C. 1320a–7e(g)(2)) is amended by inserting “,
14 and includes any individual of a long-term care facil-
15 ity or provider (other than any volunteer) that has
16 access to a patient or resident of such a facility under
17 an employment or other contract, or both, with the fa-
18 cility or provider (including individuals who are li-
19 censed or certified by the State to provide services at
20 the facility or through the provider, and nonlicensed
21 individuals, as defined by the Secretary, providing
22 services at the facility or through the provider, in-
23 cluding nurse assistants, nurse aides, home health
24 aides, individuals who provide home care, and per-
25 sonal care workers and attendants)” before the period.

1 (3) *REPORTING BY LONG-TERM CARE FACILITIES*
 2 *OR PROVIDERS.*—

3 (A) *IN GENERAL.*—Section 1128E(b)(1) (42
 4 U.S.C. 1320a–7e(b)(1)) is amended by striking
 5 “and health plan” and inserting “, health plan,
 6 and long-term care facility or provider”.

7 (B) *CORRECTION OF INFORMATION.*—Sec-
 8 tion 1128E(c)(2) (42 U.S.C. 1320a–7e(c)(2)) is
 9 amended by striking “and health plan” and in-
 10 serting “, health plan, and long-term care facil-
 11 ity or provider”.

12 (4) *ACCESS TO REPORTED INFORMATION.*—Sec-
 13 tion 1128E(d)(1) (42 U.S.C. 1320a–7e(d)(1)) is
 14 amended by striking “and health plans” and insert-
 15 ing “, health plans, and long-term care facilities or
 16 providers”.

17 (5) *MANDATORY CHECK OF DATABASE BY LONG-*
 18 *TERM CARE FACILITIES OR PROVIDERS.*—Section
 19 1128E(d) (42 U.S.C. 1320a–7e(d)) is amended by
 20 adding at the end the following:

21 “(3) *MANDATORY CHECK OF DATABASE BY LONG-*
 22 *TERM CARE FACILITIES OR PROVIDERS.*—A long-term
 23 care facility or provider shall check the database
 24 maintained under this section prior to hiring under
 25 an employment or other contract, or both, (other than

1 *in a provisional status) any individual as an em-*
 2 *ployee of such a facility or provider who will have ac-*
 3 *cess to a patient or resident of the facility or provider*
 4 *(including individuals who are licensed or certified*
 5 *by the State to provide services at the facility or*
 6 *through the provider, and nonlicensed individuals, as*
 7 *defined by the Secretary, that will provide services at*
 8 *the facility or through the provider, including nurse*
 9 *assistants, nurse aides, home health aides, individuals*
 10 *who provide home care, and personal care workers*
 11 *and attendants).”.*

12 *(6) DEFINITION OF LONG-TERM CARE FACILITY*
 13 *OR PROVIDER.—Section 1128E(g) (42 U.S.C. 1320a–*
 14 *7e(g)) is amended by adding at the end the following:*

15 *“(6) LONG-TERM CARE FACILITY OR PRO-*
 16 *VIDER.—The term ‘long-term care facility or pro-*
 17 *vider’ means a skilled nursing facility (as defined in*
 18 *section 1819(a)), a nursing facility (as defined in sec-*
 19 *tion 1919(a)), a home health agency, a provider of*
 20 *hospice care (as defined in section 1861(dd)(1)), a*
 21 *long-term care hospital (as described in section*
 22 *1886(d)(1)(B)(iv)), an intermediate care facility for*
 23 *the mentally retarded (as defined in section 1905(d)),*
 24 *or any other facility or entity that provides, or is a*
 25 *provider of, long-term care services, home health serv-*

1 *ices, or hospice care (including routine home care and*
 2 *other services included in hospice care under title*
 3 *XVIII), and receives payment for such services under*
 4 *the medicare program under title XVIII or the med-*
 5 *icaid program under title XIX.”.*

6 (7) *AUTHORIZATION OF APPROPRIATIONS.—*
 7 *There is authorized to be appropriated to carry out*
 8 *the amendments made by this subsection, \$10,200,000*
 9 *for fiscal year 2004.*

10 (f) *PREVENTION AND TRAINING DEMONSTRATION*
 11 *PROJECT.—*

12 (1) *ESTABLISHMENT.—The Secretary of Health*
 13 *and Human Services shall establish a demonstration*
 14 *program to provide grants to develop information on*
 15 *best practices in patient abuse prevention training*
 16 *(including behavior training and interventions) for*
 17 *managers and staff of hospital and health care facili-*
 18 *ties.*

19 (2) *ELIGIBILITY.—To be eligible to receive a*
 20 *grant under paragraph (1), an entity shall be a pub-*
 21 *lic or private nonprofit entity and prepare and sub-*
 22 *mit to the Secretary of Health and Human Services*
 23 *an application at such time, in such manner, and*
 24 *containing such information as the Secretary may re-*
 25 *quire.*

1 (3) *USE OF FUNDS.*—Amounts received under a
2 grant under this subsection shall be used to—

3 (A) *examine ways to improve collaboration*
4 *between State health care survey and provider*
5 *certification agencies, long-term care ombudsman*
6 *programs, the long-term care industry, and local*
7 *community members;*

8 (B) *examine patient care issues relating to*
9 *regulatory oversight, community involvement,*
10 *and facility staffing and management with a*
11 *focus on staff training, staff stress management,*
12 *and staff supervision;*

13 (C) *examine the use of patient abuse pre-*
14 *vention training programs by long-term care en-*
15 *tities, including the training program developed*
16 *by the National Association of Attorneys Gen-*
17 *eral, and the extent to which such programs are*
18 *used; and*

19 (D) *identify and disseminate best practices*
20 *for preventing and reducing patient abuse.*

21 (4) *AUTHORIZATION OF APPROPRIATIONS.*—
22 *There is authorized to be appropriated such sums as*
23 *may be necessary to carry out this subsection.*

24 (g) *EFFECTIVE DATE.*—

1 (1) *IN GENERAL.*—*With respect to a skilled nurs-*
 2 *ing facility (as defined in section 1819(a) of the So-*
 3 *cial Security Act (42 U.S.C. 1395i–3(a)) or a nursing*
 4 *facility (as defined in section 1919(a) of the Social*
 5 *Security Act (42 U.S.C. 1396r(a)), this section and*
 6 *the amendments made by this section shall take effect*
 7 *on the date that is the earlier of—*

8 (A) *6 months after the effective date of final*
 9 *regulations promulgated to carry out this section*
 10 *and such amendments; or*

11 (B) *January 1, 2006.*

12 (2) *LONG-TERM CARE FACILITIES AND PRO-*
 13 *VIDERS.*—*With respect to a long-term care facility or*
 14 *provider (as defined in section 1128E(g)(6) of the So-*
 15 *cial Security Act (42 U.S.C. 1320a–7e(g)(6)) (as*
 16 *added by subsection (e)), this section and the amend-*
 17 *ments made by this section shall take effect on the*
 18 *date that is the earlier of—*

19 (A) *18 months after the effective date of*
 20 *final regulations promulgated to carry out this*
 21 *section and such amendments; or*

22 (B) *January 1, 2007.*

23 **SEC. 637. OFFICE OF RURAL HEALTH POLICY IMPROVE-**
 24 **MENTS.**

25 Section 711(b) (42 U.S.C. 912(b)) is amended—

1 (1) in paragraph (3), by striking “and” after the
2 comma at the end;

3 (2) in paragraph (4), by inserting “and” after
4 the comma at the end; and

5 (3) by inserting after paragraph (4) the fol-
6 lowing new paragraph:

7 “(5) administer grants, cooperative agreements,
8 and contracts to provide technical assistance and
9 other activities as necessary to support activities re-
10 lated to improving health care in rural areas.”.

11 ***TITLE VII—ACCESS TO AFFORD-*** 12 ***ABLE PHARMACEUTICALS***

13 ***SEC. 701. SHORT TITLE.***

14 *This title may be cited as the “Greater Access to Af-*
15 *fordable Pharmaceuticals Act”.*

16 ***SEC. 702. 30-MONTH STAY-OF-EFFECTIVENESS PERIOD.***

17 (a) *ABBREVIATED NEW DRUG APPLICATIONS.*—*Sec-*
18 *tion 505(j) of the Federal Food, Drug, and Cosmetic Act*
19 *(21 U.S.C. 355(j)) is amended—*

20 (1) in paragraph (2), by striking subparagraph
21 (B) and inserting the following:

22 “(B) *NOTICE OF OPINION THAT PATENT IS INVALID OR*
23 *WILL NOT BE INFRINGED.*—

24 “(i) *AGREEMENT TO GIVE NOTICE.*—*An appli-*
25 *cant that makes a certification described in subpara-*

1 *graph (A)(vii)(IV) shall include in the application a*
 2 *statement that the applicant will give notice as re-*
 3 *quired by this subparagraph.*

4 “(ii) *TIMING OF NOTICE.*—*An applicant that*
 5 *makes a certification described in subparagraph*
 6 *(A)(vii)(IV) shall give notice as required under this*
 7 *subparagraph—*

8 “(I) *if the certification is in the applica-*
 9 *tion, not later than 20 days after the date of the*
 10 *postmark on the notice with which the Secretary*
 11 *informs the applicant that the application has*
 12 *been filed; or*

13 “(II) *if the certification is in an amend-*
 14 *ment or supplement to the application, at the*
 15 *time at which the applicant submits the amend-*
 16 *ment or supplement, regardless of whether the*
 17 *applicant has already given notice with respect*
 18 *to another such certification contained in the ap-*
 19 *plication or in an amendment or supplement to*
 20 *the application.*

21 “(iii) *RECIPIENTS OF NOTICE.*—*An applicant re-*
 22 *quired under this subparagraph to give notice shall*
 23 *give notice to—*

24 “(I) *each owner of the patent that is the*
 25 *subject of the certification (or a representative of*

1 *the owner designated to receive such a notice);*
 2 *and*

3 *“(II) the holder of the approved application*
 4 *under subsection (b) for the drug that is claimed*
 5 *by the patent or a use of which is claimed by the*
 6 *patent (or a representative of the holder des-*
 7 *ignated to receive such a notice).*

8 *“(iv) CONTENTS OF NOTICE.—A notice required*
 9 *under this subparagraph shall—*

10 *“(I) state that an application that contains*
 11 *data from bioavailability or bioequivalence stud-*
 12 *ies has been submitted under this subsection for*
 13 *the drug with respect to which the certification*
 14 *is made to obtain approval to engage in the com-*
 15 *mercial manufacture, use, or sale of the drug be-*
 16 *fore the expiration of the patent referred to in*
 17 *the certification; and*

18 *“(II) include a detailed statement of the fac-*
 19 *tual and legal basis of the opinion of the appli-*
 20 *cant that the patent is invalid or will not be in-*
 21 *fringed.”; and*

22 *(2) in paragraph (5)—*

23 *(A) in subparagraph (B)—*

24 *(i) by striking “under the following”*
 25 *and inserting “by applying the following to*

1 *each certification made under paragraph*
2 *(2)(A)(vii)”; and*

3 *(ii) in clause (iii)—*

4 *(I) in the first sentence, by strik-*
5 *ing “unless” and all that follows and*
6 *inserting “unless, before the expiration*
7 *of 45 days after the date on which the*
8 *notice described in paragraph (2)(B) is*
9 *received, an action is brought for in-*
10 *fringement of the patent that is the*
11 *subject of the certification and for*
12 *which information was submitted to*
13 *the Secretary under subsection (b)(1)*
14 *or (c)(2) before the date on which the*
15 *application (excluding an amendment*
16 *or supplement to the application),*
17 *which the Secretary later determines to*
18 *be substantially complete, was sub-*
19 *mitted.”; and*

20 *(II) in the second sentence—*

21 *(aa) by striking subclause (I)*

22 *and inserting the following:*

23 *“(I) if before the expiration of such period*
24 *the district court decides that the patent is in-*
25 *valid or not infringed (including any substantive*

1 *determination that there is no cause of action for*
2 *patent infringement or invalidity), the approval*
3 *shall be made effective on—*

4 *“(aa) the date on which the court en-*
5 *ters judgment reflecting the decision; or*

6 *“(bb) the date of a settlement order or*
7 *consent decree signed and entered by the*
8 *court stating that the patent that is the sub-*
9 *ject of the certification is invalid or not in-*
10 *fringed;”;*

11 *(bb) by striking subclause*

12 *(II) and inserting the following:*

13 *“(II) if before the expiration of such period*
14 *the district court decides that the patent has been*
15 *infringed—*

16 *“(aa) if the judgment of the district*
17 *court is appealed, the approval shall be*
18 *made effective on—*

19 *“(AA) the date on which the court*
20 *of appeals decides that the patent is*
21 *invalid or not infringed (including*
22 *any substantive determination that*
23 *there is no cause of action for patent*
24 *infringement or invalidity); or*

1 “(BB) the date of a settlement
 2 order or consent decree signed and en-
 3 tered by the court of appeals stating
 4 that the patent that is the subject of the
 5 certification is invalid or not in-
 6 fringed; or

7 “(bb) if the judgment of the district
 8 court is not appealed or is affirmed, the ap-
 9 proval shall be made effective on the date
 10 specified by the district court in a court
 11 order under section 271(e)(4)(A) of title 35,
 12 United States Code;”;

13 (cc) in subclause (III), by
 14 striking “on the date of such court
 15 decision.” and inserting “as pro-
 16 vided in subclause (I); or”; and

17 (dd) by inserting after sub-
 18 clause (III) the following:

19 “(IV) if before the expiration of such period
 20 the court grants a preliminary injunction pro-
 21 hibiting the applicant from engaging in the com-
 22 mercial manufacture or sale of the drug until the
 23 court decides the issues of patent validity and
 24 infringement and if the court decides that such

1 *patent has been infringed, the approval shall be*
 2 *made effective as provided in subclause (II).”;*

3 *(B) by redesignating subparagraphs (C)*
 4 *and (D) as subparagraphs (E) and (F), respec-*
 5 *tively; and*

6 *(C) by inserting after subparagraph (B) the*
 7 *following:*

8 *“(C) CIVIL ACTION TO OBTAIN PATENT CER-*
 9 *TAINTY.—*

10 *“(i) DECLARATORY JUDGMENT ABSENT*
 11 *INFRINGEMENT ACTION.—If an owner of the*
 12 *patent or the holder of the approved appli-*
 13 *cation under subsection (b) for the drug that*
 14 *is claimed by the patent or a use of which*
 15 *is claimed by the patent does not bring a*
 16 *civil action against the applicant for in-*
 17 *fringement of the patent on or before the*
 18 *date that is 45 days after the date on which*
 19 *the notice given under paragraph (2)(B)*
 20 *was received, the applicant may bring a*
 21 *civil action against the owner or holder (but*
 22 *not against any owner or holder that has*
 23 *brought such a civil action against that ap-*
 24 *plicant, unless that civil action was dis-*
 25 *missed without prejudice) for a declaratory*

1 *judgment under section 2201 of title 28,*
 2 *United States Code, that the patent is in-*
 3 *valid or will not be infringed by the drug*
 4 *for which the applicant seeks approval.*

5 “(ii) COUNTERCLAIM TO INFRINGE-
 6 MENT ACTION.—

7 “(I) IN GENERAL.—If an owner of
 8 the patent or the holder of the ap-
 9 proved application under subsection
 10 (b) for the drug that is claimed by the
 11 patent or a use of which is claimed by
 12 the patent brings a patent infringe-
 13 ment action against the applicant, the
 14 applicant may assert a counterclaim
 15 seeking an order requiring the holder
 16 to correct or delete the patent informa-
 17 tion submitted by the holder under sub-
 18 section (b) or (c) on the ground that
 19 the patent does not claim either—

20 “(aa) the drug for which the
 21 application was approved; or

22 “(bb) an approved method of
 23 using the drug.

24 “(II) NO INDEPENDENT CAUSE OF
 25 ACTION.—Subclause (I) does not au-

1 *thorize the assertion of a claim de-*
 2 *scribed in subclause (I) in any civil*
 3 *action or proceeding other than a*
 4 *counterclaim described in subclause*
 5 *(I).*

6 *“(iii) NO DAMAGES.—An applicant*
 7 *shall not be entitled to damages in a civil*
 8 *action under subparagraph (i) or a counter-*
 9 *claim under subparagraph (ii).”.*

10 *(b) APPLICATIONS GENERALLY.—Section 505 of the*
 11 *Federal Food, Drug, and Cosmetic Act (21 U.S.C. 355) is*
 12 *amended—*

13 *(1) in subsection (b), by striking paragraph (3)*
 14 *and inserting the following:*

15 *“(3) NOTICE OF OPINION THAT PATENT IS INVALID OR*
 16 *WILL NOT BE INFRINGED.—*

17 *“(A) AGREEMENT TO GIVE NOTICE.—An appli-*
 18 *cant that makes a certification described in para-*
 19 *graph (2)(A)(iv) shall include in the application a*
 20 *statement that the applicant will give notice as re-*
 21 *quired by this paragraph.*

22 *“(B) TIMING OF NOTICE.—An applicant that*
 23 *makes a certification described in paragraph*
 24 *(2)(A)(iv) shall give notice as required under this*
 25 *paragraph—*

1 “(i) if the certification is in the applica-
2 tion, not later than 20 days after the date of the
3 postmark on the notice with which the Secretary
4 informs the applicant that the application has
5 been filed; or

6 “(ii) if the certification is in an amendment
7 or supplement to the application, at the time at
8 which the applicant submits the amendment or
9 supplement, regardless of whether the applicant
10 has already given notice with respect to another
11 such certification contained in the application or
12 in an amendment or supplement to the applica-
13 tion.

14 “(C) *RECIPIENTS OF NOTICE.*—An applicant re-
15 quired under this paragraph to give notice shall give
16 notice to—

17 “(i) each owner of the patent that is the
18 subject of the certification (or a representative of
19 the owner designated to receive such a notice);
20 and

21 “(ii) the holder of the approved application
22 under this subsection for the drug that is claimed
23 by the patent or a use of which is claimed by the
24 patent (or a representative of the holder des-
25 ignated to receive such a notice).

1 “(D) *CONTENTS OF NOTICE.*—A notice required
2 under this paragraph shall—

3 “(i) state that an application that contains
4 data from bioavailability or bioequivalence stud-
5 ies has been submitted under this subsection for
6 the drug with respect to which the certification
7 is made to obtain approval to engage in the com-
8 mercial manufacture, use, or sale of the drug be-
9 fore the expiration of the patent referred to in
10 the certification; and

11 “(ii) include a detailed statement of the fac-
12 tual and legal basis of the opinion of the appli-
13 cant that the patent is invalid or will not be in-
14 fringed.”; and

15 (2) in subsection (c)(3)—

16 (A) in the first sentence, by striking “under
17 the following” and inserting “by applying the
18 following to each certification made under sub-
19 section (b)(2)(A)(iv)”;

20 (B) in subparagraph (C)—

21 (i) in the first sentence, by striking
22 “unless” and all that follows and inserting
23 “unless, before the expiration of 45 days
24 after the date on which the notice described
25 in subsection (b)(3) is received, an action is

brought for infringement of the patent that is the subject of the certification and for which information was submitted to the Secretary under paragraph (2) or subsection (b)(1) before the date on which the application (excluding an amendment or supplement to the application) was submitted.”;

(ii) in the second sentence—

(I) by striking “paragraph (3)(B)” and inserting “subsection (b)(3)”;

(II) by striking clause (i) and inserting the following:

“(i) if before the expiration of such period the district court decides that the patent is invalid or not infringed (including any substantive determination that there is no cause of action for patent infringement or invalidity), the approval shall be made effective on—

“(I) the date on which the court enters judgment reflecting the decision; or

“(II) the date of a settlement order or consent decree signed and entered by the court stating that the patent that is the sub-

1 *ject of the certification is invalid or not in-*
2 *fringed;”;*

3 *(III) by striking clause (ii) and*
4 *inserting the following:*

5 *“(ii) if before the expiration of such period*
6 *the district court decides that the patent has been*
7 *infringed—*

8 *“(I) if the judgment of the district*
9 *court is appealed, the approval shall be*
10 *made effective on—*

11 *“(aa) the date on which the court*
12 *of appeals decides that the patent is*
13 *invalid or not infringed (including*
14 *any substantive determination that*
15 *there is no cause of action for patent*
16 *infringement or invalidity); or*

17 *“(bb) the date of a settlement*
18 *order or consent decree signed and en-*
19 *tered by the court of appeals stating*
20 *that the patent that is the subject of the*
21 *certification is invalid or not in-*
22 *fringed; or*

23 *“(II) if the judgment of the district*
24 *court is not appealed or is affirmed, the ap-*
25 *proval shall be made effective on the date*

1 *specified by the district court in a court*
2 *order under section 271(e)(4)(A) of title 35,*
3 *United States Code;”;*

4 *(IV) in clause (iii), by striking*
5 *“on the date of such court decision.”*
6 *and inserting “as provided in clause*
7 *(i); or”; and*

8 *(V) by inserting after clause (iii),*
9 *the following:*

10 *“(iv) if before the expiration of such period*
11 *the court grants a preliminary injunction pro-*
12 *hibiting the applicant from engaging in the com-*
13 *mercial manufacture or sale of the drug until the*
14 *court decides the issues of patent validity and*
15 *infringement and if the court decides that such*
16 *patent has been infringed, the approval shall be*
17 *made effective as provided in clause (ii).”;* and

18 *(iii) in the third sentence, by striking*
19 *“paragraph (3)(B)” and inserting “sub-*
20 *section (b)(3)”;*

21 *(C) by redesignating subparagraph (D) as*
22 *subparagraph (E); and*

23 *(D) by inserting after subparagraph (C) the*
24 *following:*

1 “(D) *CIVIL ACTION TO OBTAIN PATENT CER-*
 2 *TAINTY.*—

3 “(i) *DECLARATORY JUDGMENT ABSENT*
 4 *INFRINGEMENT ACTION.*—*If an owner of the*
 5 *patent or the holder of the approved appli-*
 6 *cation under subsection (b) for the drug that*
 7 *is claimed by the patent or a use of which*
 8 *is claimed by the patent does not bring a*
 9 *civil action against the applicant for in-*
 10 *fringement of the patent on or before the*
 11 *date that is 45 days after the date on which*
 12 *the notice given under subsection (b)(3) was*
 13 *received, the applicant may bring a civil*
 14 *action against the owner or holder (but not*
 15 *against any owner or holder that has*
 16 *brought such a civil action against that ap-*
 17 *plicant, unless that civil action was dis-*
 18 *missed without prejudice) for a declaratory*
 19 *judgment under section 2201 of title 28,*
 20 *United States Code, that the patent is in-*
 21 *valid or will not be infringed by the drug*
 22 *for which the applicant seeks approval.*

23 “(ii) *COUNTERCLAIM TO INFRINGE-*
 24 *MENT ACTION.*—

1 “(I) *IN GENERAL.*—If an owner of
 2 the patent or the holder of the ap-
 3 proved application under subsection
 4 (b) for the drug that is claimed by the
 5 patent or a use of which is claimed by
 6 the patent brings a patent infringe-
 7 ment action against the applicant, the
 8 applicant may assert a counterclaim
 9 seeking an order requiring the holder
 10 to correct or delete the patent informa-
 11 tion submitted by the holder under sub-
 12 section (b) or this subsection on the
 13 ground that the patent does not claim
 14 either—

15 “(aa) the drug for which the
 16 application was approved; or

17 “(bb) an approved method of
 18 using the drug.

19 “(II) *NO INDEPENDENT CAUSE OF*
 20 *ACTION.*—Subclause (I) does not au-
 21 thorize the assertion of a claim de-
 22 scribed in subclause (I) in any civil
 23 action or proceeding other than a
 24 counterclaim described in subclause
 25 (I).

1 “(iii) *NO DAMAGES.*—*An applicant*
 2 *shall not be entitled to damages in a civil*
 3 *action under clause (i) or a counterclaim*
 4 *under clause (ii).’’.*

5 (c) *INFRINGEMENT ACTIONS.*—*Section 271(e) of title*
 6 *35, United States Code, is amended by adding at the end*
 7 *the following:*

8 “(5) *The filing of an application described in*
 9 *paragraph (2) that includes a certification under sub-*
 10 *section (b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section*
 11 *505 of the Federal Food, Drug, and Cosmetic Act (21*
 12 *U.S.C. 355), and the failure of the owner of the pat-*
 13 *ent to bring an action for infringement of a patent*
 14 *that is the subject of the certification before the expi-*
 15 *ration of 45 days after the date on which the notice*
 16 *given under subsection (b)(3) or (j)(2)(B) of that sec-*
 17 *tion is received, shall establish an actual controversy*
 18 *between the applicant and the patent owner sufficient*
 19 *to confer subject matter jurisdiction in the courts of*
 20 *the United States in any action brought by the appli-*
 21 *cant under section 2201 of title 28 for a declaratory*
 22 *judgment that any patent that is the subject of the*
 23 *certification is invalid or not infringed.’’.*

24 (d) *APPLICABILITY.*—

1 (1) *IN GENERAL.*—*Except as provided in para-*
2 *graphs (2) and (3), the amendments made by sub-*
3 *sections (a), (b), and (c) apply to any proceeding*
4 *under section 505 of the Federal Food, Drug, and*
5 *Cosmetic Act (21 U.S.C. 355) that is pending on or*
6 *after the date of enactment of this Act regardless of*
7 *the date on which the proceeding was commenced or*
8 *is commenced.*

9 (2) *NOTICE OF OPINION THAT PATENT IS IN-*
10 *VALID OR WILL NOT BE INFRINGED.*—*The amend-*
11 *ments made by subsections (a)(1) and (b)(1) apply*
12 *with respect to any certification under subsection*
13 *(b)(2)(A)(iv) or (j)(2)(A)(vii)(IV) of section 505 of the*
14 *Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
15 *355) after the date of enactment of this Act in an ap-*
16 *plication filed under subsection (b)(2) or (j) of that*
17 *section or in an amendment or supplement to an ap-*
18 *plication filed under subsection (b)(2) or (j) of that*
19 *section.*

20 (3) *EFFECTIVE DATE OF APPROVAL.*—*The*
21 *amendments made by subsections (a)(2)(A)(ii)(I) and*
22 *(b)(2)(B)(i) apply with respect to any patent infor-*
23 *mation submitted under subsection (b)(1) or (c)(2) of*
24 *section 505 of the Federal Food, Drug, and Cosmetic*

1 *Act (21 U.S.C. 355) made after the date of enactment*
 2 *of this Act.*

3 **SEC. 703. FORFEITURE OF 180-DAY EXCLUSIVITY PERIOD.**

4 *(a) IN GENERAL.—Section 505(j)(5) of the Federal*
 5 *Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(5)) (as*
 6 *amended by section 702) is amended—*

7 *(1) in subparagraph (B), by striking clause (iv)*
 8 *and inserting the following:*

9 *“(iv) 180-DAY EXCLUSIVITY PERIOD.—*

10 *“(I) DEFINITIONS.—In this paragraph:*

11 *“(aa) 180-DAY EXCLUSIVITY PERIOD.—*

12 *The term ‘180-day exclusivity period’*
 13 *means the 180-day period ending on the*
 14 *day before the date on which an application*
 15 *submitted by an applicant other than a*
 16 *first applicant could become effective under*
 17 *this clause.*

18 *“(bb) FIRST APPLICANT.—The term*
 19 *‘first applicant’ means an applicant that,*
 20 *on the first day on which a substantially*
 21 *complete application containing a certifi-*
 22 *cation described in paragraph*
 23 *(2)(A)(vii)(IV) is submitted for approval of*
 24 *a drug, submits a substantially complete*
 25 *application containing a certification de-*

scribed in paragraph (2)(A)(vii)(IV) for the drug.

“(cc) *SUBSTANTIALLY COMPLETE APPLICATION.*—As used in this subsection, the term ‘substantially complete application’ means an application under this subsection that on its face is sufficiently complete to permit a substantive review and contains all the information required by paragraph (2)(A).

“(dd) *TENTATIVE APPROVAL.*—

“(AA) *IN GENERAL.*—The term ‘tentative approval’ means notification to an applicant by the Secretary that an application under this subsection meets the requirements of paragraph (2)(A), but cannot receive effective approval because the application does not meet the requirements of this subparagraph, there is a period of exclusivity for the listed drug under subparagraph (E) or section 505A, or there is a 7-year period of exclusivity for the listed drug under section 527.

1 “(BB) *LIMITATION.*—A drug that
 2 is granted tentative approval by the
 3 Secretary is not an approved drug and
 4 shall not have an effective approval
 5 until the Secretary issues an approval
 6 after any necessary additional review
 7 of the application.

8 “(II) *EFFECTIVENESS OF APPLICATION.*—
 9 Subject to subparagraph (D), if the application
 10 contains a certification described in paragraph
 11 (2)(A)(vii)(IV) and is for a drug for which a
 12 first applicant has submitted an application
 13 containing such a certification, the application
 14 shall be made effective on the date that is 180
 15 days after the date of the first commercial mar-
 16 keting of the drug (including the commercial
 17 marketing of the listed drug) by any first appli-
 18 cant.”; and
 19 (2) by inserting after subparagraph (C) the fol-
 20 lowing:

21 “(D) *FORFEITURE OF 180-DAY EXCLUSIVITY*
 22 *PERIOD.*—

23 “(i) *DEFINITION OF FORFEITURE*
 24 *EVENT.*—In this subparagraph, the term
 25 ‘forfeiture event’, with respect to an appli-

1 *cation under this subsection, means the oc-*
 2 *currence of any of the following:*

3 “(I) *FAILURE TO MARKET.*—*The*
 4 *first applicant fails to market the drug*
 5 *by the later of—*

6 “(aa) *the earlier of the date*
 7 *that is—*

8 “(AA) *75 days after the*
 9 *date on which the approval*
 10 *of the application of the first*
 11 *applicant is made effective*
 12 *under subparagraph (B)(iii);*
 13 *or*

14 “(BB) *30 months after*
 15 *the date of submission of the*
 16 *application of the first appli-*
 17 *cant; or*

18 “(bb) *with respect to the first*
 19 *applicant or any other applicant*
 20 *(which other applicant has re-*
 21 *ceived tentative approval), the*
 22 *date that is 75 days after the date*
 23 *as of which, as to each of the pat-*
 24 *ents with respect to which the first*
 25 *applicant submitted a certifi-*

1 *cation qualifying the first appli-*
2 *cant for the 180-day exclusivity*
3 *period under subparagraph*
4 *(B)(iv), at least 1 of the following*
5 *has occurred:*

6 *“(AA) In an infringe-*
7 *ment action brought against*
8 *that applicant with respect*
9 *to the patent or in a declara-*
10 *tory judgment action brought*
11 *by that applicant with re-*
12 *spect to the patent, a court*
13 *enters a final decision from*
14 *which no appeal (other than*
15 *a petition to the Supreme*
16 *Court for a writ of certio-*
17 *rari) has been or can be*
18 *taken that the patent is in-*
19 *valid or not infringed.*

20 *“(BB) In an infringe-*
21 *ment action or a declaratory*
22 *judgment action described in*
23 *subitem (AA), a court signs a*
24 *settlement order or consent*
25 *decree that enters a final*

1 *judgment that includes a*
2 *finding that the patent is in-*
3 *valid or not infringed.*

4 “(CC) *The patent ex-*
5 *pires.*

6 “(DD) *The patent is*
7 *withdrawn by the holder of*
8 *the application approved*
9 *under subsection (b).*

10 “(II) *WITHDRAWAL OF APPLICA-*
11 *TION.—The first applicant withdraws*
12 *the application or the Secretary con-*
13 *siders the application to have been*
14 *withdrawn as a result of a determina-*
15 *tion by the Secretary that the applica-*
16 *tion does not meet the requirements for*
17 *approval under paragraph (4).*

18 “(III) *AMENDMENT OF CERTIFI-*
19 *CATION.—The first applicant amends*
20 *or withdraws the certification for all of*
21 *the patents with respect to which that*
22 *applicant submitted a certification*
23 *qualifying the applicant for the 180-*
24 *day exclusivity period.*

1 “(IV) *FAILURE TO OBTAIN TEN-*
2 *TATIVE APPROVAL.*—*The first appli-*
3 *cant fails to obtain tentative approval*
4 *of the application within 30 months*
5 *after the date on which the application*
6 *is filed, unless the failure is caused by*
7 *a change in or a review of the require-*
8 *ments for approval of the application*
9 *imposed after the date on which the*
10 *application is filed.*

11 “(V) *AGREEMENT WITH ANOTHER*
12 *APPLICANT, THE LISTED DRUG APPLI-*
13 *CATION HOLDER, OR A PATENT*
14 *OWNER.*—*The first applicant enters*
15 *into an agreement with another appli-*
16 *cant under this subsection for the drug,*
17 *the holder of the application for the*
18 *listed drug, or an owner of the patent*
19 *that is the subject of the certification*
20 *under paragraph (2)(A)(vii)(IV), the*
21 *Federal Trade Commission or the At-*
22 *torney General files a complaint, and*
23 *there is a final decision of the Federal*
24 *Trade Commission or the court with*
25 *regard to the complaint from which no*

1 *appeal (other than a petition to the*
 2 *Supreme Court for a writ of certiorari)*
 3 *has been or can be taken that the*
 4 *agreement has violated the antitrust*
 5 *laws (as defined in section 1 of the*
 6 *Clayton Act (15 U.S.C. 12), except that*
 7 *the term includes section 5 of the Fed-*
 8 *eral Trade Commission Act (15 U.S.C.*
 9 *45) to the extent that that section ap-*
 10 *plies to unfair methods of competition).*

11 “(VI) *EXPIRATION OF ALL PAT-*
 12 *ENTS.—All of the patents as to which*
 13 *the applicant submitted a certification*
 14 *qualifying it for the 180-day exclu-*
 15 *sivity period have expired.*

16 “(ii) *FORFEITURE.—The 180-day ex-*
 17 *clusivity period described in subparagraph*
 18 *(B)(iv) shall be forfeited by a first appli-*
 19 *cant if a forfeiture event occurs with respect*
 20 *to that first applicant.*

21 “(iii) *SUBSEQUENT APPLICANT.—If all*
 22 *first applicants forfeit the 180-day exclu-*
 23 *sivity period under clause (ii)—*

24 “(I) *approval of any application*
 25 *containing a certification described in*

1 paragraph (2)(A)(vii)(IV) shall be
 2 made effective in accordance with sub-
 3 paragraph (B)(iii); and

4 “(II) no applicant shall be eligible
 5 for a 180-day exclusivity period.”.

6 (b) *EFFECTIVE DATE.*—

7 (1) *IN GENERAL.*—Except as provided in para-
 8 graph (2), the amendment made by subsection (a)
 9 shall be effective only with respect to an application
 10 filed under section 505(j) of the Federal Food, Drug,
 11 and Cosmetic Act (21 U.S.C. 355(j)) after the date of
 12 enactment of this Act for a listed drug for which no
 13 certification under section 505(j)(2)(A)(vii)(IV) of
 14 that Act was made before the date of enactment of this
 15 Act.

16 (2) *COLLUSIVE AGREEMENTS.*—If a forfeiture
 17 event described in section 505(j)(5)(D)(i)(V) of that
 18 Act occurs in the case of an applicant, the applicant
 19 shall forfeit the 180-day period under section
 20 505(j)(5)(B)(iv) of that Act without regard to when
 21 the first certification under section
 22 505(j)(2)(A)(vii)(IV) of that Act for the listed drug
 23 was made.

24 (3) *DECISION OF A COURT WHEN THE 180-DAY*
 25 *EXCLUSIVITY PERIOD HAS NOT BEEN TRIGGERED.*—

1 *With respect to an application filed before, on, or*
 2 *after the date of enactment of this Act for a listed*
 3 *drug for which a certification under section*
 4 *505(j)(2)(A)(vii)(IV) of that Act was made before the*
 5 *date of enactment of this Act and for which neither*
 6 *of the events described in subclause (I) or (II) of sec-*
 7 *tion 505(j)(5)(B)(iv) of that Act (as in effect on the*
 8 *day before the date of enactment of this Act) has oc-*
 9 *curred on or before the date of enactment of this Act,*
 10 *the term “decision of a court” as used in clause (iv)*
 11 *of section 505(j)(5)(B) of that Act means a final deci-*
 12 *sion of a court from which no appeal (other than a*
 13 *petition to the Supreme Court for a writ of certio-*
 14 *rari) has been or can be taken.*

15 **SEC. 704. BIOAVAILABILITY AND BIOEQUIVALENCE.**

16 (a) *IN GENERAL.*—Section 505(j)(8) of the Federal
 17 *Food, Drug, and Cosmetic Act (21 U.S.C. 355(j)(8)) is*
 18 *amended—*

19 (1) *by striking subparagraph (A) and inserting*
 20 *the following:*

21 “(A)(i) *The term ‘bioavailability’ means the rate*
 22 *and extent to which the active ingredient or thera-*
 23 *peutic ingredient is absorbed from a drug and be-*
 24 *comes available at the site of drug action.*

1 “(ii) *For a drug that is not intended to be ab-*
 2 *sorbed into the bloodstream, the Secretary may assess*
 3 *bioavailability by scientifically valid measurements*
 4 *intended to reflect the rate and extent to which the ac-*
 5 *tive ingredient or therapeutic ingredient becomes*
 6 *available at the site of drug action.*”; and

7 (2) *by adding at the end the following:*

8 “(C) *For a drug that is not intended to be ab-*
 9 *sorbed into the bloodstream, the Secretary may estab-*
 10 *lish alternative, scientifically valid methods to show*
 11 *bioequivalence if the alternative methods are expected*
 12 *to detect a significant difference between the drug and*
 13 *the listed drug in safety and therapeutic effect.*”.

14 (b) *EFFECT OF AMENDMENT.*—*The amendment made*
 15 *by subsection (a) does not alter the standards for approval*
 16 *of drugs under section 505(j) of the Federal Food, Drug,*
 17 *and Cosmetic Act (21 U.S.C. 355(j)).*

18 **SEC. 705. REMEDIES FOR INFRINGEMENT.**

19 *Section 287 of title 35, United States Code, is amended*
 20 *by adding at the end the following:*

21 “(d) *CONSIDERATION.*—*In making a determination*
 22 *with respect to remedy brought for infringement of a patent*
 23 *that claims a drug or a method or using a drug, the court*
 24 *shall consider whether information on the patent was filed*
 25 *as required under 21 U.S.C. 355 (b) or (c), and, if such*

1 *information was required to be filed but was not, the court*
 2 *may refuse to award treble damages under section 284.”.*

3 **SEC. 706. CONFORMING AMENDMENTS.**

4 *Section 505A of the Federal Food, Drug, and Cosmetic*
 5 *Act (21 U.S.C. 355a) is amended—*

6 *(1) in subsections (b)(1)(A)(i) and (c)(1)(A)(i),*
 7 *by striking “(j)(5)(D)(ii)” each place it appears and*
 8 *inserting “(j)(5)(F)(ii)”;*

9 *(2) in subsections (b)(1)(A)(ii) and (c)(1)(A)(ii),*
 10 *by striking “(j)(5)(D)” each place it appears and in-*
 11 *serting “(j)(5)(F)”;* and

12 *(3) in subsections (e) and (l), by striking*
 13 *“505(j)(5)(D)” each place it appears and inserting*
 14 *“505(j)(5)(F)”.*

15 **TITLE VIII—IMPORTATION OF**
 16 **PRESCRIPTION DRUGS**

17 **SEC. 801. IMPORTATION OF PRESCRIPTION DRUGS.**

18 *(a) IN GENERAL.—Chapter VIII of the Federal Food,*
 19 *Drug, and Cosmetic Act (21 U.S.C. 381 et seq.) is amended*
 20 *by striking section 804 and inserting the following:*

21 **“SEC. 804. IMPORTATION OF PRESCRIPTION DRUGS.**

22 **“(a) DEFINITIONS.—In this section:**

23 **“(1) IMPORTER.—The term ‘importer’ means a**
 24 **pharmacist or wholesaler.**

1 “(2) *PHARMACIST.*—*The term ‘pharmacist’*
 2 *means a person licensed by a State to practice phar-*
 3 *macy, including the dispensing and selling of pre-*
 4 *scription drugs.*

5 “(3) *PRESCRIPTION DRUG.*—*The term ‘prescrip-*
 6 *tion drug’ means a drug subject to section 503(b),*
 7 *other than—*

8 “(A) *a controlled substance (as defined in*
 9 *section 102 of the Controlled Substances Act (21*
 10 *U.S.C. 802));*

11 “(B) *a biological product (as defined in sec-*
 12 *tion 351 of the Public Health Service Act (42*
 13 *U.S.C. 262));*

14 “(C) *an infused drug (including a peri-*
 15 *toneal dialysis solution);*

16 “(D) *an intravenously injected drug; or*

17 “(E) *a drug that is inhaled during surgery.*

18 “(4) *QUALIFYING LABORATORY.*—*The term*
 19 *‘qualifying laboratory’ means a laboratory in the*
 20 *United States that has been approved by the Sec-*
 21 *retary for the purposes of this section.*

22 “(5) *WHOLESALE.*—

23 “(A) *IN GENERAL.*—*The term ‘wholesaler’*
 24 *means a person licensed as a wholesaler or dis-*

1 *tributor of prescription drugs in the United*
 2 *States under section 503(e)(2)(A).*

3 “(B) *EXCLUSION.*—*The term ‘wholesaler’*
 4 *does not include a person authorized to import*
 5 *drugs under section 801(d)(1).*

6 “(b) *REGULATIONS.*—*The Secretary, after consultation*
 7 *with the United States Trade Representative and the Com-*
 8 *missioner of Customs, shall promulgate regulations permit-*
 9 *ting pharmacists and wholesalers to import prescription*
 10 *drugs from Canada into the United States.*

11 “(c) *LIMITATION.*—*The regulations under subsection*
 12 *(b) shall—*

13 “(1) *require that safeguards be in place to ensure*
 14 *that each prescription drug imported under the regu-*
 15 *lations complies with section 505 (including with re-*
 16 *spect to being safe and effective for the intended use*
 17 *of the prescription drug), with sections 501 and 502,*
 18 *and with other applicable requirements of this Act;*

19 “(2) *require that an importer of a prescription*
 20 *drug under the regulations comply with subsections*
 21 *(d)(1) and (e); and*

22 “(3) *contain any additional provisions deter-*
 23 *mined by the Secretary to be appropriate as a safe-*
 24 *guard to protect the public health or as a means to*
 25 *facilitate the importation of prescription drugs.*

1 “(d) *INFORMATION AND RECORDS.*—

2 “(1) *IN GENERAL.*—*The regulations under sub-*
3 *section (b) shall require an importer of a prescription*
4 *drug under subsection (b) to submit to the Secretary*
5 *the following information and documentation:*

6 “(A) *The name and quantity of the active*
7 *ingredient of the prescription drug.*

8 “(B) *A description of the dosage form of the*
9 *prescription drug.*

10 “(C) *The date on which the prescription*
11 *drug is shipped.*

12 “(D) *The quantity of the prescription drug*
13 *that is shipped.*

14 “(E) *The point of origin and destination of*
15 *the prescription drug.*

16 “(F) *The price paid by the importer for the*
17 *prescription drug.*

18 “(G) *Documentation from the foreign seller*
19 *specifying—*

20 “(i) *the original source of the prescrip-*
21 *tion drug; and*

22 “(ii) *the quantity of each lot of the*
23 *prescription drug originally received by the*
24 *seller from that source.*

1 “(H) *The lot or control number assigned to*
2 *the prescription drug by the manufacturer of the*
3 *prescription drug.*

4 “(I) *The name, address, telephone number,*
5 *and professional license number (if any) of the*
6 *importer.*

7 “(J)(i) *In the case of a prescription drug*
8 *that is shipped directly from the first foreign re-*
9 *cipient of the prescription drug from the manu-*
10 *facturer:*

11 “(I) *Documentation demonstrating*
12 *that the prescription drug was received by*
13 *the recipient from the manufacturer and*
14 *subsequently shipped by the first foreign re-*
15 *recipient to the importer.*

16 “(II) *Documentation of the quantity of*
17 *each lot of the prescription drug received by*
18 *the first foreign recipient demonstrating*
19 *that the quantity being imported into the*
20 *United States is not more than the quantity*
21 *that was received by the first foreign recipi-*
22 *ent.*

23 “(III)(aa) *In the case of an initial im-*
24 *ported shipment, documentation dem-*
25 *onstrating that each batch of the prescrip-*

1 *tion drug in the shipment was statistically*
2 *sampled and tested for authenticity and*
3 *degradation.*

4 *“(bb) In the case of any subsequent*
5 *shipment, documentation demonstrating*
6 *that a statistically valid sample of the ship-*
7 *ment was tested for authenticity and deg-*
8 *radation.*

9 *“(ii) In the case of a prescription drug that*
10 *is not shipped directly from the first foreign re-*
11 *cipient of the prescription drug from the manu-*
12 *facturer, documentation demonstrating that each*
13 *batch in each shipment offered for importation*
14 *into the United States was statistically sampled*
15 *and tested for authenticity and degradation.*

16 *“(K) Certification from the importer or*
17 *manufacturer of the prescription drug that the*
18 *prescription drug—*

19 *“(i) is approved for marketing in the*
20 *United States; and*

21 *“(ii) meets all labeling requirements*
22 *under this Act.*

23 *“(L) Laboratory records, including complete*
24 *data derived from all tests necessary to ensure*

1 *that the prescription drug is in compliance with*
 2 *established specifications and standards.*

3 “(M) *Documentation demonstrating that the*
 4 *testing required by subparagraphs (J) and (L)*
 5 *was conducted at a qualifying laboratory.*

6 “(N) *Any other information that the Sec-*
 7 *retary determines is necessary to ensure the pro-*
 8 *tection of the public health.*

9 “(2) *MAINTENANCE BY THE SECRETARY.—The*
 10 *Secretary shall maintain information and docu-*
 11 *mentation submitted under paragraph (1) for such*
 12 *period of time as the Secretary determines to be nec-*
 13 *essary.*

14 “(e) *TESTING.—The regulations under subsection (b)*
 15 *shall require—*

16 “(1) *that testing described in subparagraphs (J)*
 17 *and (L) of subsection (d)(1) be conducted by the im-*
 18 *porter or by the manufacturer of the prescription*
 19 *drug at a qualified laboratory;*

20 “(2) *if the tests are conducted by the importer—*

21 “(A) *that information needed to—*

22 “(i) *authenticate the prescription drug*
 23 *being tested; and*

1 “(ii) confirm that the labeling of the
 2 prescription drug complies with labeling re-
 3 quirements under this Act;

4 be supplied by the manufacturer of the prescrip-
 5 tion drug to the pharmacist or wholesaler; and

6 “(B) that the information supplied under
 7 subparagraph (A) be kept in strict confidence
 8 and used only for purposes of testing or other-
 9 wise complying with this Act; and

10 “(3) may include such additional provisions as
 11 the Secretary determines to be appropriate to provide
 12 for the protection of trade secrets and commercial or
 13 financial information that is privileged or confiden-
 14 tial.

15 “(f) *REGISTRATION OF FOREIGN SELLERS.*—Any es-
 16 tablishment within Canada engaged in the distribution of
 17 a prescription drug that is imported or offered for importa-
 18 tion into the United States shall register with the Secretary
 19 the name and place of business of the establishment.

20 “(g) *SUSPENSION OF IMPORTATION.*—The Secretary
 21 shall require that importations of a specific prescription
 22 drug or importations by a specific importer under sub-
 23 section (b) be immediately suspended on discovery of a pat-
 24 tern of importation of that specific prescription drug or by
 25 that specific importer of drugs that are counterfeit or in

1 *violation of any requirement under this section, until an*
 2 *investigation is completed and the Secretary determines*
 3 *that the public is adequately protected from counterfeit and*
 4 *violative prescription drugs being imported under sub-*
 5 *section (b).*

6 “(h) *APPROVED LABELING.*—*The manufacturer of a*
 7 *prescription drug shall provide an importer written author-*
 8 *ization for the importer to use, at no cost, the approved*
 9 *labeling for the prescription drug.*

10 “(i) *PROHIBITION OF DISCRIMINATION.*—

11 “(1) *IN GENERAL.*—*It shall be unlawful for a*
 12 *manufacturer of a prescription drug to discriminate*
 13 *against, or cause any other person to discriminate*
 14 *against, a pharmacist or wholesaler that purchases or*
 15 *offers to purchase a prescription drug from the manu-*
 16 *facturer or from any person that distributes a pre-*
 17 *scription drug manufactured by the drug manufac-*
 18 *turer.*

19 “(2) *DISCRIMINATION.*—*For the purposes of*
 20 *paragraph (1), a manufacturer of a prescription drug*
 21 *shall be considered to discriminate against a phar-*
 22 *macist or wholesaler if the manufacturer enters into*
 23 *a contract for sale of a prescription drug, places a*
 24 *limit on supply, or employs any other measure, that*
 25 *has the effect of—*

1 “(A) *providing pharmacists or wholesalers*
2 *access to prescription drugs on terms or condi-*
3 *tions that are less favorable than the terms or*
4 *conditions provided to a foreign purchaser (other*
5 *than a charitable or humanitarian organization)*
6 *of the prescription drug; or*

7 “(B) *restricting the access of pharmacists or*
8 *wholesalers to a prescription drug that is per-*
9 *mitted to be imported into the United States*
10 *under this section.*

11 “(j) *CHARITABLE CONTRIBUTIONS.—Notwithstanding*
12 *any other provision of this section, section 801(d)(1) con-*
13 *tinues to apply to a prescription drug that is donated or*
14 *otherwise supplied at no charge by the manufacturer of the*
15 *drug to a charitable or humanitarian organization (includ-*
16 *ing the United Nations and affiliates) or to a government*
17 *of a foreign country.*

18 “(k) *WAIVER AUTHORITY FOR IMPORTATION BY INDIV-*
19 *VIDUALS.—*

20 “(1) *DECLARATIONS.—Congress declares that in*
21 *the enforcement against individuals of the prohibition*
22 *of importation of prescription drugs and devices, the*
23 *Secretary should—*

1 “(A) *focus enforcement on cases in which*
 2 *the importation by an individual poses a signifi-*
 3 *cant threat to public health; and*

4 “(B) *exercise discretion to permit individ-*
 5 *uals to make such importations in circumstances*
 6 *in which—*

7 “(i) *the importation is clearly for per-*
 8 *sonal use; and*

9 “(ii) *the prescription drug or device*
 10 *imported does not appear to present an un-*
 11 *reasonable risk to the individual.*

12 “(2) *WAIVER AUTHORITY.—*

13 “(A) *IN GENERAL.—The Secretary may*
 14 *grant to individuals, by regulation or on a case-*
 15 *by-case basis, a waiver of the prohibition of im-*
 16 *portation of a prescription drug or device or*
 17 *class of prescription drugs or devices, under such*
 18 *conditions as the Secretary determines to be ap-*
 19 *propriate.*

20 “(B) *GUIDANCE ON CASE-BY-CASE WAIV-*
 21 *ERS.—The Secretary shall publish, and update*
 22 *as necessary, guidance that accurately describes*
 23 *circumstances in which the Secretary will con-*
 24 *sistently grant waivers on a case-by-case basis*
 25 *under subparagraph (A), so that individuals*

1 *may know with the greatest practicable degree of*
 2 *certainty whether a particular importation for*
 3 *personal use will be permitted.*

4 “(3) *DRUGS IMPORTED FROM CANADA.*—*In par-*
 5 *ticular, the Secretary shall by regulation grant indi-*
 6 *viduals a waiver to permit individuals to import into*
 7 *the United States a prescription drug that—*

8 “(A) *is imported from a licensed pharmacy*
 9 *for personal use by an individual, not for resale,*
 10 *in quantities that do not exceed a 90-day supply;*

11 “(B) *is accompanied by a copy of a valid*
 12 *prescription;*

13 “(C) *is imported from Canada, from a sell-*
 14 *er registered with the Secretary;*

15 “(D) *is a prescription drug approved by the*
 16 *Secretary under chapter V;*

17 “(E) *is in the form of a final finished dos-*
 18 *age that was manufactured in an establishment*
 19 *registered under section 510; and*

20 “(F) *is imported under such other condi-*
 21 *tions as the Secretary determines to be necessary*
 22 *to ensure public safety.*

23 “(l) *STUDIES; REPORTS.*—

24 “(1) *BY THE INSTITUTE OF MEDICINE OF THE*
 25 *NATIONAL ACADEMY OF SCIENCES.*—

1 “(A) *STUDY.*—

2 “(i) *IN GENERAL.*—*The Secretary shall*
3 *request that the Institute of Medicine of the*
4 *National Academy of Sciences conduct a*
5 *study of—*

6 “(I) *importations of prescription*
7 *drugs made under the regulations*
8 *under subsection (b); and*

9 “(II) *information and documenta-*
10 *tion submitted under subsection (d).*

11 “(ii) *REQUIREMENTS.*—*In conducting*
12 *the study, the Institute of Medicine shall—*

13 “(I) *evaluate the compliance of*
14 *importers with the regulations under*
15 *subsection (b);*

16 “(II) *compare the number of ship-*
17 *ments under the regulations under sub-*
18 *section (b) during the study period*
19 *that are determined to be counterfeit,*
20 *misbranded, or adulterated, and com-*
21 *pare that number with the number of*
22 *shipments made during the study pe-*
23 *riod within the United States that are*
24 *determined to be counterfeit, mis-*
25 *branded, or adulterated; and*

1 “(III) consult with the Secretary,
2 the United States Trade Representa-
3 tive, and the Commissioner of Patents
4 and Trademarks to evaluate the effect
5 of importations under the regulations
6 under subsection (b) on trade and pat-
7 ent rights under Federal law.

8 “(B) REPORT.—Not later than 2 years after
9 the effective date of the regulations under sub-
10 section (b), the Institute of Medicine shall submit
11 to Congress a report describing the findings of
12 the study under subparagraph (A).

13 “(2) BY THE COMPTROLLER GENERAL.—

14 “(A) STUDY.—The Comptroller General of
15 the United States shall conduct a study to deter-
16 mine the effect of this section on the price of pre-
17 scription drugs sold to consumers at retail.

18 “(B) REPORT.—Not later than 18 months
19 after the effective date of the regulations under
20 subsection (b), the Comptroller General of the
21 United States shall submit to Congress a report
22 describing the findings of the study under sub-
23 paragraph (A).

24 “(m) CONSTRUCTION.—Nothing in this section limits
25 the authority of the Secretary relating to the importation

1 of prescription drugs, other than with respect to section
 2 801(d)(1) as provided in this section.

3 “(n) *EFFECTIVENESS OF SECTION.*—

4 “(1) *IN GENERAL.*—If, after the date that is 1
 5 year after the effective date of the regulations under
 6 subsection (b) and before the date that is 18 months
 7 after the effective date, the Secretary submits to Con-
 8 gress a certification that, in the opinion of the Sec-
 9 retary, based on substantial evidence obtained after
 10 the effective date, the benefits of implementation of
 11 this section do not outweigh any detriment of imple-
 12 mentation of this section, this section shall cease to be
 13 effective as of the date that is 30 days after the date
 14 on which the Secretary submits the certification.

15 “(2) *PROCEDURE.*—The Secretary shall not sub-
 16 mit a certification under paragraph (1) unless, after
 17 a hearing on the record under sections 556 and 557
 18 of title 5, United States Code, the Secretary—

19 “(A)(i) determines that it is more likely
 20 than not that implementation of this section
 21 would result in an increase in the risk to the
 22 public health and safety;

23 “(ii) identifies specifically, in qualitative
 24 and quantitative terms, the nature of the in-
 25 creased risk;

1 “(iii) identifies specifically the causes of the
2 increased risk; and

3 “(iv)(I) considers whether any measures can
4 be taken to avoid, reduce, or mitigate the in-
5 creased risk; and

6 “(II) if the Secretary determines that any
7 measures described in subclause (I) would re-
8 quire additional statutory authority, submits to
9 Congress a report describing the legislation that
10 would be required;

11 “(B) identifies specifically, in qualitative
12 and quantitative terms, the benefits that would
13 result from implementation of this section (in-
14 cluding the benefit of reductions in the cost of
15 covered products to consumers in the United
16 States, allowing consumers to procure needed
17 medication that consumers might not otherwise
18 be able to procure without foregoing other neces-
19 sities of life); and

20 “(C)(i) compares in specific terms the det-
21 riment identified under subparagraph (A) with
22 the benefits identified under subparagraph (B);
23 and

24 “(ii) determines that the benefits do not out-
25 weigh the detriment.

1 “(o) *AUTHORIZATION OF APPROPRIATIONS.*—*There*
 2 *are authorized to be appropriated such sums as are nec-*
 3 *essary to carry out this section.*”.

4 (b) *CONFORMING AMENDMENTS.*—*The Federal Food,*
 5 *Drug, and Cosmetic Act is amended—*

6 (1) *in section 301(aa) (21 U.S.C. 331(aa)), by*
 7 *striking “covered product in violation of section 804”*
 8 *and inserting “prescription drug in violation of sec-*
 9 *tion 804”; and*

10 (2) *in section 303(a)(6) (21 U.S.C. 333(a)(6)), by*
 11 *striking “covered product pursuant to section 804(a)”*
 12 *and inserting “prescription drug under section*
 13 *804(b)”.*

14 (c) *CONDITIONS.*—*This section shall become effective*
 15 *only if the Secretary of Health and Human Services cer-*
 16 *tifies to the Congress that the implementation of this section*
 17 *will—*

18 (1) *pose no additional risk to the public’s health*
 19 *and safety; and*

20 (2) *result in a significant reduction in the cost*
 21 *of covered products to the American consumer.*

1 ***TITLE IX—DRUG COMPETITION***
2 ***ACT OF 2003***

3 ***SEC. 901. SHORT TITLE.***

4 *This title may be cited as the “Drug Competition Act*
5 *of 2003”.*

6 ***SEC. 902. FINDINGS.***

7 *Congress finds that—*

8 *(1) prescription drug prices are increasing at an*
9 *alarming rate and are a major worry of many senior*
10 *citizens and American families;*

11 *(2) there is a potential for companies with pat-*
12 *ent rights regarding brand name drugs and compa-*
13 *nies which could manufacture generic versions of such*
14 *drugs to enter into financial deals that could tend to*
15 *restrain trade and greatly reduce competition and in-*
16 *crease prescription drug expenditures for American*
17 *citizens; and*

18 *(3) enhancing competition among these compa-*
19 *nies can significantly reduce prescription drug ex-*
20 *penditures for Americans.*

21 ***SEC. 903. PURPOSES.***

22 *The purposes of this title are—*

23 *(1) to provide timely notice to the Department of*
24 *Justice and the Federal Trade Commission regarding*
25 *agreements between companies with patent rights re-*

1 *garding brand name drugs and companies which*
 2 *could manufacture generic versions of such drugs; and*
 3 *(2) by providing timely notice, to enhance the ef-*
 4 *fectiveness and efficiency of the enforcement of the*
 5 *antitrust and competition laws of the United States.*

6 **SEC. 904. DEFINITIONS.**

7 *In this title:*

8 *(1) ANDA.—The term “ANDA” means an Ab-*
 9 *breivated New Drug Application, as defined under*
 10 *section 201(aa) of the Federal Food, Drug, and Cos-*
 11 *metic Act (21 U.S.C. 321(aa)).*

12 *(2) ASSISTANT ATTORNEY GENERAL.—The term*
 13 *“Assistant Attorney General” means the Assistant At-*
 14 *torney General in charge of the Antitrust Division of*
 15 *the Department of Justice.*

16 *(3) BRAND NAME DRUG.—The term “brand name*
 17 *drug” means a drug approved under section 505(c) of*
 18 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 19 *355(c)).*

20 *(4) BRAND NAME DRUG COMPANY.—The term*
 21 *“brand name drug company” means the party that*
 22 *received Food and Drug Administration approval to*
 23 *market a brand name drug pursuant to an NDA,*
 24 *where that drug is the subject of an ANDA, or a*
 25 *party owning or controlling enforcement of any pat-*

1 *ent listed in the Approved Drug Products With*
 2 *Therapeutic Equivalence Evaluations of the Food and*
 3 *Drug Administration for that drug, under section*
 4 *505(b) of the Federal Food, Drug, and Cosmetic Act*
 5 *(21 U.S.C. 355(b)).*

6 (5) *COMMISSION.*—*The term “Commission”*
 7 *means the Federal Trade Commission.*

8 (6) *GENERIC DRUG.*—*The term “generic drug”*
 9 *means a product that the Food and Drug Adminis-*
 10 *tration has approved under section 505(j) of the Fed-*
 11 *eral Food, Drug, and Cosmetic Act (21 U.S.C.*
 12 *355(j)).*

13 (7) *GENERIC DRUG APPLICANT.*—*The term “ge-*
 14 *neric drug applicant” means a person who has filed*
 15 *or received approval for an ANDA under section*
 16 *505(j) of the Federal Food, Drug, and Cosmetic Act*
 17 *(21 U.S.C. 355(j)).*

18 (8) *NDA.*—*The term “NDA” means a New Drug*
 19 *Application, as defined under section 505(b) et seq. of*
 20 *the Federal Food, Drug, and Cosmetic Act (21 U.S.C.*
 21 *355(b) et seq.)*

22 **SEC. 905. NOTIFICATION OF AGREEMENTS.**

23 (a) *IN GENERAL.*—

24 (1) *REQUIREMENT.*—*A generic drug applicant*
 25 *that has submitted an ANDA containing a certifi-*

1 *cation under section 505(j)(2)(vii)(IV) of the Federal*
 2 *Food, Drug, and Cosmetic Act (21 U.S.C.*
 3 *355(j)(2)(vii)(IV)) and a brand name drug company*
 4 *that enter into an agreement described in paragraph*
 5 *(2), prior to the generic drug that is the subject of the*
 6 *application entering the market, shall each file the*
 7 *agreement as required by subsection (b).*

8 (2) *DEFINITION.—An agreement described in*
 9 *this paragraph is an agreement regarding—*

10 (A) *the manufacture, marketing or sale of*
 11 *the brand name drug that is the subject of the ge-*
 12 *neric drug applicant’s ANDA;*

13 (B) *the manufacture, marketing or sale of*
 14 *the generic drug that is the subject of the generic*
 15 *drug applicant’s ANDA; or*

16 (C) *the 180-day period referred to in section*
 17 *505(j)(5)(B)(iv) of the Federal Food, Drug, and*
 18 *Cosmetic Act (21 U.S.C. 355(j)(5)(B)(iv)) as it*
 19 *applies to such ANDA or to any other ANDA*
 20 *based on the same brand name drug.*

21 (b) *FILING.—*

22 (1) *AGREEMENT.—The generic drug applicant*
 23 *and the brand name drug company entering into an*
 24 *agreement described in subsection (a)(2) shall file*
 25 *with the Assistant Attorney General and the Commis-*

1 *sion the text of any such agreement, except that the*
 2 *generic drug applicant and the brand-name drug*
 3 *company shall not be required to file an agreement*
 4 *that solely concerns—*

5 *(A) purchase orders for raw material sup-*
 6 *plies;*

7 *(B) equipment and facility contracts;*

8 *(C) employment or consulting contracts; or*

9 *(D) packaging and labeling contracts.*

10 *(2) OTHER AGREEMENTS.—The generic drug ap-*
 11 *plicant and the brand name drug company entering*
 12 *into an agreement described in subsection (a)(2) shall*
 13 *file with the Assistant Attorney General and the Com-*
 14 *mission the text of any other agreements not described*
 15 *in subsection (a)(2) between the generic drug appli-*
 16 *cant and the brand name drug company which are*
 17 *contingent upon, provide a contingent condition for,*
 18 *or are otherwise related to an agreement which must*
 19 *be filed under this title.*

20 *(3) DESCRIPTION.—In the event that any agree-*
 21 *ment required to be filed by paragraph (1) or (2) has*
 22 *not been reduced to text, both the generic drug appli-*
 23 *cant and the brand name drug company shall file*
 24 *written descriptions of the non-textual agreement or*

1 *agreements that must be filed sufficient to reveal all*
2 *of the terms of the agreement or agreements.*

3 **SEC. 906. FILING DEADLINES.**

4 *Any filing required under section 5 shall be filed with*
5 *the Assistant Attorney General and the Commission not*
6 *later than 10 business days after the date the agreements*
7 *are executed.*

8 **SEC. 907. DISCLOSURE EXEMPTION.**

9 *Any information or documentary material filed with*
10 *the Assistant Attorney General or the Commission pursuant*
11 *to this title shall be exempt from disclosure under section*
12 *552 of title 5, and no such information or documentary ma-*
13 *terial may be made public, except as may be relevant to*
14 *any administrative or judicial action or proceeding. Noth-*
15 *ing in this section is intended to prevent disclosure to either*
16 *body of Congress or to any duly authorized committee or*
17 *subcommittee of the Congress.*

18 **SEC. 908. ENFORCEMENT.**

19 *(a) CIVIL PENALTY.—Any brand name drug company*
20 *or generic drug applicant which fails to comply with any*
21 *provision of this title shall be liable for a civil penalty of*
22 *not more than \$11,000, for each day during which such en-*
23 *tity is in violation of this title. Such penalty may be recov-*
24 *ered in a civil action brought by the United States, or*
25 *brought by the Commission in accordance with the proce-*

1 *dures established in section 16(a)(1) of the Federal Trade*
 2 *Commission Act (15 U.S.C. 56(a)).*

3 (b) *COMPLIANCE AND EQUITABLE RELIEF.—If any*
 4 *brand name drug company or generic drug applicant fails*
 5 *to comply with any provision of this title, the United States*
 6 *district court may order compliance, and may grant such*
 7 *other equitable relief as the court in its discretion deter-*
 8 *mines necessary or appropriate, upon application of the As-*
 9 *sistant Attorney General or the Commission.*

10 **SEC. 909. RULEMAKING.**

11 *The Commission, with the concurrence of the Assistant*
 12 *Attorney General and by rule in accordance with section*
 13 *553 of title 5 United States Code, consistent with the pur-*
 14 *poses of this title—*

15 (1) *may define the terms used in this title;*

16 (2) *may exempt classes of persons or agreements*
 17 *from the requirements of this title; and*

18 (3) *may prescribe such other rules as may be*
 19 *necessary and appropriate to carry out the purposes*
 20 *of this title.*

21 **SEC. 910. SAVINGS CLAUSE.**

22 *Any action taken by the Assistant Attorney General*
 23 *or the Commission, or any failure of the Assistant Attorney*
 24 *General or the Commission to take action, under this title*
 25 *shall not bar any proceeding or any action with respect*

1 *to any agreement between a brand name drug company and*
 2 *a generic drug applicant at any time under any other pro-*
 3 *vision of law, nor shall any filing under this title constitute*
 4 *or create a presumption of any violation of any antitrust*
 5 *or competition laws.*

6 **SEC. 911. EFFECTIVE DATE.**

7 *This title shall—*

8 *(1) take effect 30 days after the date of enact-*
 9 *ment of this title; and*

10 *(2) shall apply to agreements described in section*
 11 *905 that are entered into 30 days after the date of en-*
 12 *actment of this title.*

Amend the title so as to read: “An Act to amend title XVIII of the Social Security Act to provide for a voluntary prescription drug benefit under the medicare program and to strengthen and improve the medicare program, and for other purposes.”.

Attest:

Secretary.

108TH CONGRESS
1ST SESSION

H. R. 1

AMENDMENTS